2023

Commercial FUS Manufacturers

Focused Ultrasound Foundation

Overview

In the wake of exponential advancement, the industry has surpassed the inflection point, reflecting a shift in the mindset from "if" focused ultrasound will have a critical place in the therapeutic armamentarium to "when" it will be widely available as a mainstream standard of care.

Additionally, we are seeing increasing evidence that the field is transitioning from primarily a science-based research environment to commercialization with patient treatment spaces focused on marketing and sales. As this transition gains momentum, we want to keep pace with the data points and metrics needed to understand and evaluate this global commercialization, so that we may accurately analyze the information and disseminate our findings to all stakeholders. This chapter is a deep dive on the 16 companies that have commercial products available to treat 32 different indications. Information on companies that are still at the research and development stage can be found in Chapter 8 and/or on our website fusfoundation.org/for-industry.

A special thank you to all the industry partners in this space who, year after year, provide information on their companies so that we can collate the data in aggregate to better understand the field.

Approvals may have changed or been updated since publication. For the most up-to-date information please visit: fusfoundation.org/the-foundation/programs/regulatory-approvals-search.

X. Commercial FUS Manufacturers

Indication Approvals by Manufacturer

Manufacturer	North America	Europe	Asia	South America	Oceania	Africa
Acoustic MedSystems[1]	1	–	–	–	–	–
Alpinion Medical Systems	–	1	2	–	–	–
Changjiangyuan Technology Development	–	1	–	–	–	–
Chongqing Haifu Medical Technology	–	11	10	–	–	–
EDAP TMS	2	1	1	1	–	–
EpiSonica	–	–	1	–	–	–
EyeTechCare	–	1	1	–	–	–
Insightec	7	12	14	11	11	–
Profound Medical	4	6	5	3	3	–
Shanghai A&S Science Technology Development	–	1	5	–	–	–
Shende Medical Equipment Technology[3]	–	1	–	–	–	–
Shenzhen PRO-HITU Medical Technology	–	1	4	–	–	–
Sonablate	2	2	2	2	2	1
Theraclion	–	3	4	–	–	–
TOOsonix[4]	–	1	–	–	–	–
Wuxi Haiying Electronic Medical Systems	–	–	1	–	–	–

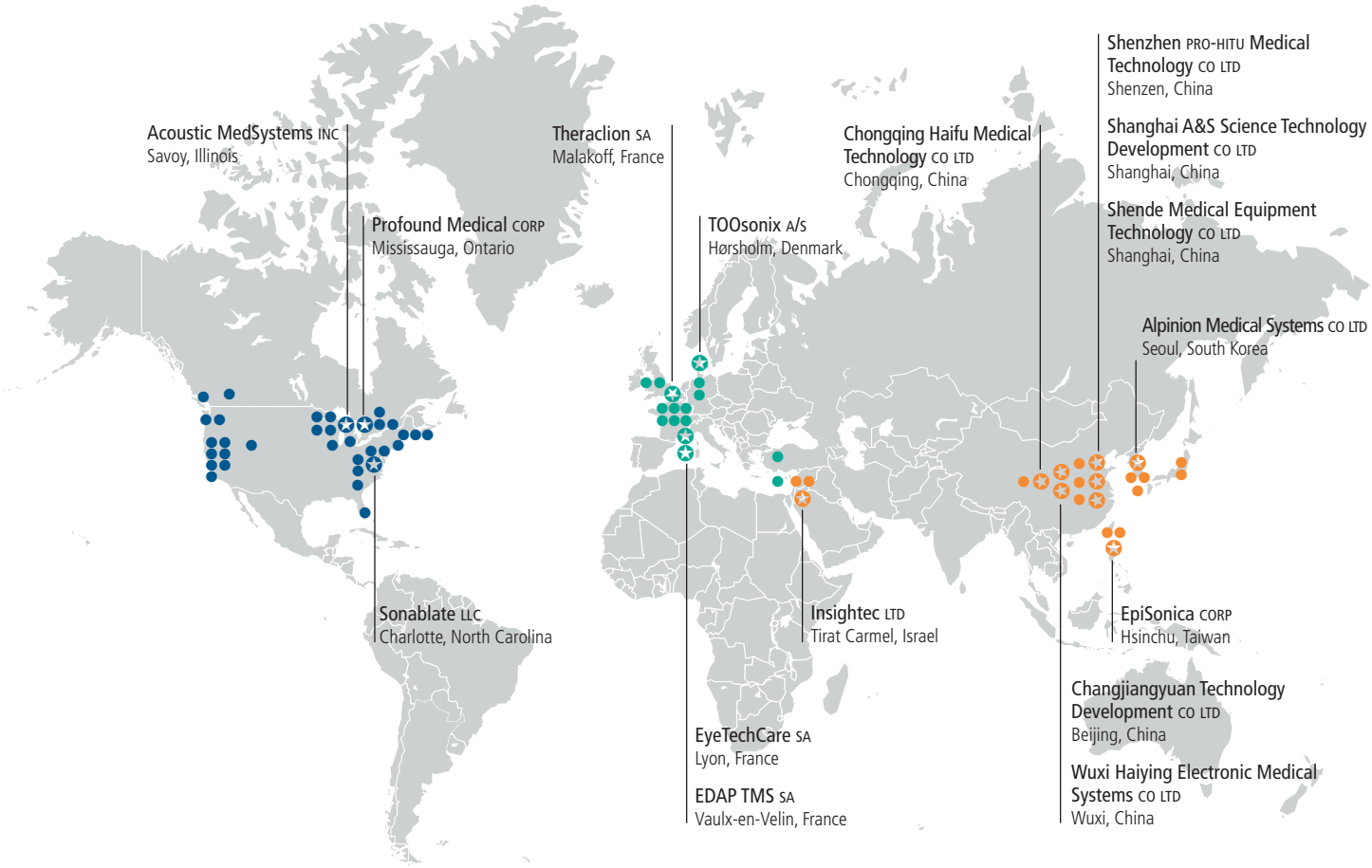
Summary of Global Approvals

39
Regulatory agencies

337
Approvals worldwide

1 Approval is for soft tissue ablation, excluding prostate.
2 Approval is for tumor ablation.
3 Approved indication(s) unknown
4 Approval are for aesthetic indications, which are not tracked by the Foundation.

Clinical Device Manufacturers with Regulatory Approvals



Clinical device manufacturers that have a device or devices with regulatory approvals by regional location.
Company listings of devices, approved indications, and regulatory agencies granting approvals are found on the subsequent pages.

Location of clinical device manufacturers without approved devices by region.

Regulatory Approvals for Companies by Region and Indication

North America

Acoustic MedSystems
Soft tissue ablation, excluding prostate

EDAP TMS
Benign prostatic hyperplasia
Prostate cancer

Insightec
Benign prostatic hyperplasia
Bone metastases
Essential tremor
Parkinson's disease, dyskinesia
Parkinson's disease, tremor
Prostate cancer
Uterine fibroids

Profound Medical
Benign prostatic hyperplasia
Osteoid osteoma
Prostate cancer
Uterine fibroids

Sonablate
Benign prostatic hyperplasia
Prostate cancer

Europe

Alpinion Medical Systems
Uterine fibroids

Changjiangyuan Technology Development
Tumor ablation

Chongqing Haifu Medical Technology
Breast tumors, malignant
Kidney tumors
Liver metastases
Liver tumors
Osteoid osteoma
Pancreatic tumors
Rhinitis
Soft tissue cancer
Soft tissue tumors, benign
Uterine adenomyosis
Uterine fibroids

EDAP TMS
Prostate cancer

EyeTechCare
Glaucoma

Insightec
Arthritis, facetogenic
Bone cancer
Bone metastases
Bone tumors, benign
Essential tremor
Multiple myeloma
Neuropathic pain
Parkinson's disease, dyskinesia
Parkinson's disease, tremor
Prostate cancer
Uterine adenomyosis
Uterine fibroids

Profound Medical
Bone metastases
Desmoid tumors
Osteoid osteoma
Prostate cancer
Uterine adenomyosis
Uterine fibroids

Shanghai A&S
Uterine fibroids

Shende Medical Equipment Technology
Indication(s) unknown

Shenzhen PRO-HITU Medical
Uterine fibroids

Sonablate
Benign prostatic hyperplasia
Prostate cancer

Theraclion
Breast tumors, benign
Thyroid nodules
Varicose veins

TOOsonix
Aesthetic indications

Asia

Alpinion Medical Systems
Uterine adenomyosis
Uterine fibroids

Chongqing Haifu Medical Technology
Breast tumors, malignant
Cervicitis
Kidney tumors
Liver tumors
Osteoid osteoma
Pancreatic tumors
Rhinitis
Soft tissue cancer
Soft tissue tumors, benign
Uterine fibroids

EDAP TMS
Prostate cancer

EpiSonica
Soft tissue cancer

EyeTechCare
Glaucoma

Insightec
Arthritis, facetogenic
Bone cancer
Bone metastases
Bone tumors, benign
Depression
Essential tremor
Multiple myeloma
Neuropathic pain
Obsessive-compulsive disorder
Parkinson's disease, dyskinesia
Parkinson's disease, tremor
Prostate cancer
Uterine adenomyosis
Uterine fibroids

Profound Medical
Bone metastases
Osteoid osteoma
Prostate cancer
Uterine adenomyosis
Uterine fibroids

Shanghai A&S
Bone metastases
Breast tumors, malignant
Liver tumors
Soft tissue cancer
Uterine fibroids

Shenzhen PRO-HITU Medical
Hyperplasia of the vulva
Lichen sclerosis
Uterine adenomyosis
Uterine fibroids

Sonablate
Benign prostatic hyperplasia
Prostate cancer

Theraclion
Breast tumors, benign
Breast tumors, malignant
Thyroid nodules
Varicose veins

Wuxi Haiying Electronic Medical
Uterine fibroids

South America

EDAP TMS
Prostate cancer

Insightec
Arthritis, facetogenic
Bone cancer
Bone metastases
Bone tumors, benign
Essential tremor
Multiple myeloma
Neuropathic pain
Parkinson's disease, tremor
Prostate cancer
Uterine adenomyosis
Uterine fibroids

Profound Medical
Bone metastases
Uterine adenomyosis
Uterine fibroids

Sonablate
Benign prostatic hyperplasia
Prostate cancer

Oceania

Insightec
Arthritis, facetogenic
Bone cancer
Bone metastases
Bone tumors, benign
Essential tremor
Multiple myeloma
Neuropathic pain
Parkinson's disease, tremor
Prostate cancer
Uterine adenomyosis
Uterine fibroids

Profound Medical
Bone metastases
Uterine adenomyosis
Uterine fibroids

Sonablate
Benign prostatic hyperplasia
Prostate cancer

Africa

Sonablate
Prostate cancer

Clinical Device Manufacturers with Regulatory Approvals

Acoustic MedSystems INC

Devices

2	1		
Total devices	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
ACOUSTx	—	Ultrasound, CT-fluoroscopy, MRI and 3D targeting	—
TheraVision	✚	US guidance	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
—			
Soft tissue ablation, excluding prostate[1]	North America	United States	FDA, 2016

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Approval language does not further delineate tissue type.

Clinical Device Manufacturers with Regulatory Approvals continued

Alpinion Medical Systems CO LTD

Devices

2	1		
Total devices	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Alpius 900	✚	US guidance	—
VIFU2000	—	US guidance	—

Approvals

2	2	2	3
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Women's health			
Uterine adenomyosis	Asia	South Korea	MFDS, 2018
Uterine fibroids	Europe Asia	Europe South Korea	CE Marking, 2016 MFDS, 2014

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Alpinion Medical Systems CO LTD continued

Clinical research

2	1	1	2
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Pancreatic tumors, malignant	1	1	1
Women's health			
Uterine fibroids	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Changjiangyuan Technology Development CO LTD

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
NUTAS - Non-invasive Ultrasound Tumor Ablation System	✚	US guidance	US guidance
SUPER Knife-Focused Beam Therapy System	✚	MR & US guidance	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
—			
Tumor ablation[1]	Europe	Europe	CE Marking, 2012
Tumor ablation[1]	Europe	Europe	CE Marking, 2018

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Approval language does not specify tumor type.

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD

Devices

8 Total devices

4 Approved devices

Name	Status	Treatment guidance	Planning guidance
CZB	✚	US guidance	—
CZF	✚	US guidance	—
CZG300	—	US guidance	—
JC	✚	US guidance	—
JC200	✚	US guidance	—
JC200D	—	US guidance	—
JC300	—	US guidance	—
LCA200	—	Unguided	—

Approvals

12 Approved indications

2 Regions

4 Countries

33 Total approvals*

Indication	Region	Country	Agency and date
Gastrointestinal			
Liver metastases	Europe	Europe	CE Marking, 2005
Liver tumors	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
	Asia	South Korea	MFDS, 2014

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Gastrointestinal continued			
Pancreatic tumors	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
	Asia	South Korea	MFDS, 2014
Musculoskeletal			
Osteoid osteoma	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
Soft tissue cancer	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
Soft tissue tumors, benign	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
Pulmonary			
Rhinitis	Europe	Europe	CE Marking, 2006
	Asia	China	NMPA, 1999
Urological			
Kidney tumors	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
Women's health			
Breast tumors, malignant	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
Cervicitis	Asia	China	NMPA, 1999
Uterine adenomyosis	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health continued			
Uterine fibroids	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2011
	Asia	China	NMPA, 1999
	Asia	South Korea	MFDS, 2014

Clinical research

17	2	7	17
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	1	3	4
Pancreatic tumors	1	1	1
Pancreatic tumors, malignant	1	4	5
Musculoskeletal			
Desmoid tumors	1	1	1
Osteoid osteoma	1	1	1
Sacral chordoma	1	1	1
Soft tissue cancer	1	1	2
Soft tissue tumors, benign	1	3	3
Neurological			
Neuropathic pain	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Clinical research continued

Indication	Region	Country	Site
Pulmonary			
Rhinitis	1	1	1
Urological			
Kidney tumors	1	2	2
Prostate cancer	1	1	1
Women's health			
Breast tumors, malignant	1	3	4
Cervical tumors	1	1	1
Retained placenta	1	1	1
Uterine adenomyosis	1	2	3
Uterine fibroids	2	4	7

Clinical Device Manufacturers with Regulatory Approvals continued

EDAP TMS SA

Devices

3	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Ablatherm	✚	Image fusion	US guidance
EDAP (Prototype)	—	US guidance	US guidance
Focal One	✚	Image fusion	MR guidance, US guidance, biopsies

Approvals

2	4	6	12
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	United States	FDA, 2015
Prostate cancer	North America	Canada	Health Canada, 2003
	North America	United States	FDA, 2015
	Europe	Europe	CE Marking, 2013
	Europe	Russia	Roszdravnadzor, 2002
	Asia	South Korea	MFDS, 2002
	South America	Brazil	ANVISA, 2016

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

EDAP TMS SA continued

Clinical research

3	2	6	28
Indications	Regions	Countries	Sites

Indication	Region	Country	Site
Urological			
Benign prostatic hyperplasia	1	1	1
Prostate cancer	2	6	26
Women's health			
Endometriosis	1	1	1

> **EDAP TMS** designs, produces, and markets medical equipment dedicated to minimally invasive therapies based on robotic therapeutic ultrasound. Our lead product, Focal One®, combines the latest technologies in imaging and treatment modalities."
>
> — EDAP TMS SA

Clinical Device Manufacturers with Regulatory Approvals continued

EpiSonica CORP

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
ArcBLATE (ARC-100M)	✚	MR	MR

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Soft tissue cancer	Asia	Taiwan	FDA, 2016

> **EpiSonica Corp** is a leading company that is focusing on development of a supine and prone MRgHIFU system. Our ArcBlate system provides treatment for uterine fibroids and uterine adenomyosis disease as well as the application of pain palliation for bone metastases."
>
> — EpiSonica CORP

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

EyeTechCare SA

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
EyeOP1	✚	Unguided	—

Approvals

1	2	2	2
Approved indication	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Ophthalmological			
Glaucoma	Europe	Europe	CE Marking, 2011
	Asia	China	NMPA, 2017

Clinical research

1	2	4	4
Indication	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Ophthalmological			
Glaucoma	2	4	4

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD

Devices

3	3		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Exablate Body	✚	MR guidance	MR guidance
Exablate Neuro	✚	MR guidance	MR/CT guidance
Exablate Prostate	✚	MR guidance	MR guidance

Approvals

15	5	28	166
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Arthritis, facetogenic	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Kazakhstan	NCEM, 2019
	Asia	South Korea	MFDS, 2015
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Musculoskeletal continued			
Bone cancer	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Israel	AMAR, 2008
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006
Bone metastases	North America	Canada	Health Canada, 2013
	North America	United States	FDA, 2012
	Europe	Belarus	MOH, 2021
	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Kazakhstan	NCEM, 2019
	Asia	Kuwait	MOH FDCD, 2021
	Asia	Saudi Arabia	SFDA, 2021
	Asia	South Korea	MFDS, 2015
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Musculoskeletal continued			
Bone tumors, benign	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006
Multiple myeloma	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006
Neurological			
Depression	Asia	South Korea	MFDS, 2015
Essential tremor	North America	Canada	Health Canada, 2016
	North America	United States	FDA, 2016
	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Europe	United Kingdom	MHRA, 2022
	Asia	China	NMPA, 2021
	Asia	Hong Kong	MDD, 2020
	Asia	India	CDSCO, 2021
	Asia	Israel	AMAR, 2015
	Asia	Japan	MHLW, 20160

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Neurological continued			
Essential tremor continued	Asia	Kazakhstan	NCEM, 2020
	Asia	Philippines	FDA, 2018
	Asia	Singapore	HSA, 2021
	Asia	South Korea	MFDS, 2015
	Asia	Taiwan	FDA, 2017
	Asia	Thailand	FDA, 2020
	Asia	United Arab Emirates	MOHAP, 2022
	South America	Argentina	ANMAT, 2019
	South America	Brazil	ANVISA, 2020
	South America	Chile	ANAMED, 2018
	South America	Colombia	INVIMA, 2021
	South America	Peru	DIGEMED, 2021
	Oceania	Australia	TGA, 2015
Neuropathic pain	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Europe	United Kingdom	MHRA, 2022
	Asia	Hong Kong	MDD, 2020
	Asia	India	CDSCO, 2021
	Asia	Israel	AMAR, 2015
	Asia	Kazakhstan	NCEM, 2020
	Asia	Philippines	FDA, 2018
	Asia	South Korea	MFDS, 2015
	Asia	Thailand	FDA, 2020
	Asia	United Arab Emirates	MOHAP, 2022
	South America	Argentina	ANMAT, 2019
	South America	Brazil	ANVISA, 2020
	South America	Chile	ANAMED, 2018
	South America	Colombia	INVIMA, 2021
	South America	Peru	DIGEMED, 2021
	Oceania	Australia	TGA, 2015

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Neurological continued			
Obsessive-compulsive disorder	Asia	South Korea	MFDS, 2015
Parkinson's disease, dyskinesia	North America	United States	FDA, 2021
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Japan	MHLW, 2020
	Asia	South Korea	MFDS, 2015
Parkinson's disease, tremor	North America	United States	FDA, 2018
	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Europe	United Kingdom	MHRA, 2022
	Asia	China	NMPA, 2021
	Asia	Hong Kong	MDD, 2020
	Asia	India	CDSCO, 2021
	Asia	Israel	AMAR, 2015
	Asia	Japan	MHLW, 2020
	Asia	Kazakhstan	NCEM, 2020
	Asia	Philippines	FDA, 2018
	Asia	Singapore	HSA, 2021
	Asia	South Korea	MFDS, 2015
	Asia	Taiwan	FDA, 2022
	Asia	Thailand	FDA, 2020
	Asia	United Arab Emirates	MOHAP, 2022
	South America	Argentina	ANMAT, 2019
	South America	Brazil	ANVISA, 2020
	South America	Chile	ANAMED, 2018
	South America	Colombia	INVIMA, 2021
	South America	Peru	DIGEMED, 2021
	Oceania	Australia	TGA, 2015

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	United States	FDA, 2021
Prostate cancer	North America	United States	FDA, 2021
	Europe	Belarus	MOH, 2021
	Europe	Europe	CE Marking, 2016
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Israel	AMAR, 2022
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2016
	Oceania	New Zealand	MEDSAFE, 2016
Women's health			
Uterine adenomyosis	Europe	Europe	CE Marking, 2006
	Europe	Turkey	TITUBB, 2017
	Asia	Hong Kong	MDD, 2020
	Asia	Israel	AMAR, 2008
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health continued			
Uterine fibroids	North America	Canada	Health Canada, 2013
	North America	United States	FDA, 2004
	Europe	Belarus	MOH, 2021
	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2006
	Europe	Turkey	TITUBB, 2017
	Asia	China	NMPA, 2013
	Asia	Hong Kong	MDD, 2020
	Asia	Israel	AMAR, 2003
	Asia	Japan	MHLW, 2006
	Asia	Kazakhstan	NCEM, 2019
	Asia	Kuwait	MOH FDCD, 2021
	Asia	Saudi Arabia	SFDA, 2021
	Asia	Singapore	HSA, 2012
	Asia	South Korea	MFDS, 2011
	Asia	Taiwan	FDA, 2006
	Asia	Thailand	FDA, 2020
	South America	Chile	ANAMED, 2018
	Oceania	Australia	TGA, 2006
	Oceania	New Zealand	MEDSAFE, 2006

> **Insightec** is a global healthcare company creating the next generation of patient care by realizing the therapeutic power of acoustic energy. Insightec is dedicated to the research and commercial application of focused ultrasound in multiple indications"
>
> — Insightec INC

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Clinical research

40	4	17	76
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	1	1	2
Pancreatic tumors, malignant	2	2	2
Miscellaneous			
Head & neck tumors	1	2	2
Musculoskeletal			
Arthritis, facetogenic	2	5	6
Arthritis, knee	1	1	1
Bone cancer	1	1	2
Bone metastases	3	7	12
Bone tumors, benign	1	1	1
Osteoid osteoma	2	3	5
Soft tissue cancer	2	2	2
Soft tissue tumors, benign	2	2	2
Neurological			
Alzheimer's disease	2	3	9
Amyotrophic lateral sclerosis	1	1	1
Astrocytoma	1	1	2
Brain metastases, breast cancer	1	1	1
Brain metastases, lung cancer	1	2	4
Brain metastases, melanoma	1	1	1
Brain tumors, general	1	2	2

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Clinical research continued

Indication	Region	Country	Site
Neurological continued			
Cancer pain	1	1	1
Depression	2	2	2
Dystonia	1	3	3
Dystonia, hand	1	1	1
Epilepsy	2	2	7
Essential tremor	3	10	17
Glioblastoma	3	6	16
Multiple sclerosis	1	1	1
Neurofibromatosis	1	1	1
Neuropathic pain	1	1	1
Obsessive-compulsive disorder	1	1	2
Painful amputation neuromas	1	1	1
Parkinson's disease, dyskinesia	3	4	14
Parkinson's disease, tremor	3	7	12
Parkinson's disease, underlying cause	1	1	1
Pontine glioma	1	2	4
Tremor, orthostatic	1	1	1
Trigeminal neuralgia	1	1	1
Urological			
Prostate cancer	2	2	6
Women's health			
Endometriosis	1	1	1
Uterine adenomyosis	3	4	5
Uterine fibroids	4	11	15

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Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Sonalleve	✚	MR guidance	MR guidance
TULSA-PRO	✚	MR guidance	MR guidance

Approvals[1]

7	5	12	33
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Bone metastases	Europe	Europe	CE Marking, 2011
	Asia	Malaysia	MDA, 2015
	Asia	Singapore	HSA, 2021
	Asia	Vietnam	DMEW, 2010
	South America	Argentina	ANMAT, 2012
	Oceania	Australia	TGA, 2012
	Oceania	New Zealand	MEDSAFE, 2012
Desmoid tumors	Europe	Europe	CE Marking, 2021
Osteoid osteoma	North America	United States	FDA, 2020
	Europe	Europe	CE Marking, 2020
	Asia	Singapore	HSA, 2021

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Approvals may have changed or been updated since publication. For the most up-to-date information please visit: fusfoundation.org/the-foundation/programs/regulatory-approvals-search.

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Approvals continued

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	United States	FDA, 2019
Prostate cancer	North America	Canada	Health Canada, 2019
	North America	United States	FDA, 2019
	Europe	Europe	CE Marking, 2016
	Asia	Singapore	HSA, 2019
Women's health			
Uterine adenomyosis	Europe	Europe	CE Marking, 2010
	Asia	Malaysia	MDA, 2015
	Asia	Vietnam	DMEW, 2010
	South America	Argentina	ANMAT, 2012
	Oceania	Australia	TGA, 2012
	Oceania	New Zealand	MEDSAFE, 2012
Uterine fibroids	North America	Canada	Health Canada, 2013
	Europe	Europe	CE Marking, 2009
	Asia	China	NMPA, 2018
	Asia	Malaysia	MDA, 2015
	Asia	Saudi Arabia	SFDA, 2015
	Asia	Singapore	HSA, 2021
	Asia	South Korea	MFDS, 2012
	Asia	Vietnam	DMEW, 2010
	South America	Argentina	ANMAT, 2012
	Oceania	Australia	TGA, 2012
	Oceania	New Zealand	MEDSAFE, 2012

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Clinical research

22	3	10	28
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	1	1	1
Pancreatic tumors, malignant	1	1	2
Miscellaneous			
Head & neck tumors	1	1	1
Multiple tumors[1]	1	1	1
Musculoskeletal			
Arthritis, facetogenic	1	1	1
Arthritis, sacroiliac	1	1	1
Bone cancer	1	2	4
Bone metastases	2	5	6
Bone tumors, benign	1	2	2
Desmoid tumors	2	5	6
Osteoid osteoma	2	2	3
Plantar fasciitis	1	1	1
Soft tissue cancer	1	2	2
Soft tissue tumors, benign	2	2	2
Neurological			
Neuroblastoma	1	1	1
Urological			
Benign prostatic hyperplasia	1	1	1
Prostate cancer	2	6	15

1 Protocols inclusive of more than one indication

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Clinical research continued

Indication	Region	Country	Site
Women's health			
Breast tumors, malignant	2	2	2
Uterine adenomyosis	2	3	3
Uterine fibroids	2	5	7
Vaginal tumors	1	1	1

> **Profound** develops customizable, incision-free ablative therapies which combine real-time MRI, thermal ultrasound, autonomous robotics, and closed-loop process control to change the standard of care for physicians and patients."
>
> — Profound Medical CORP

Clinical Device Manufacturers with Regulatory Approvals continued

Shanghai A&S Science Technology Development CO, LTD

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
HIFUNIT9000	✚	US guidance	MR guidance

Approvals

5	2	4	8
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Gastrointestinal			
Liver tumors	Asia	China	NMPA, 2002
Musculoskeletal			
Bone metastases	Asia	China	NMPA, 2002
Soft tissue cancer	Asia	China	NMPA, 2002
Women's health			
Breast tumors, malignant	Asia	China	NMPA, 2002
Uterine fibroids	Europe Asia Asia Asia	Europe China South Korea Thailand	CE Marking, 2008 NMPA, 2002 MFDS, 2007 FDA, 2013

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Shanghai A&S Science Technology Development CO, LTD continued

Clinical research

1 Indication	1 Region	1 Country	1 Site

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	1	1	1

> **Shanghai A&S Science Technology Development** is a leading company focused on high intensity focused ultrasound for tumor ablation with ultrasound guidance. Based in Shanghai, A&S has expanded business in Asia with over 200 installations."
>
> — Shanghai A&S Science Technology Development CO LTD

Clinical Device Manufacturers with Regulatory Approvals continued

Shende Medical Equipment Technology CO LTD

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Aceso	✚	MR guidance	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
—			
—[1]	Europe	Europe	CE Marking, 2020

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Indication(s) unknown

Clinical Device Manufacturers with Regulatory Approvals continued

Shende Medical Equipment Technology CO LTD continued

Clinical research

4	1	1	4
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Musculoskeletal			
Bone metastases	1	1	3
Women's health			
Breast tumors, benign	1	1	2
Uterine adenomyosis	1	1	3
Uterine fibroids	1	1	3

Clinical Device Manufacturers with Regulatory Approvals continued

Shenzhen PRO-HITU Medical Technology CO, LTD

Devices

5 Total devices

3 Approved devices

Name	Status	Treatment guidance	Planning guidance
PRO2008	✚	US guidance	US guidance
PRO300	✚	US guidance	US guidance
PRO3008	—	US guidance	US guidance
PRO5G	✚	Other guidance	Visual guidance
UT1000	—	Unguided	Not used

Approvals

4 Approved indications

2 Regions

4 Countries

10 Total approvals*

Indication	Region	Country	Agency and date
Women's health			
Hyperplasia of the vulva	Asia	China	NMPA, 2019
Lichen sclerosis	Asia	China	NMPA, 2019
Uterine adenomyosis	Asia Asia	China South Korea	NMPA, 2012 MFDS, 2016
Uterine fibroids	Europe Asia Asia	Europe China Taiwan	CE Marking, 2012 MDA, 2012 FDA, 2018

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Shenzhen PRO-HITU Medical Technology CO, LTD continued

Clinical research

2	1	1	4
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Women's health			
Uterine adenomyosis	1	1	3
Uterine fibroids	1	1	3

> **Shenzen PRO–HITU Medical Technology** was established in 2003, focusing on R&D of large ultrasonic treatment equipment. Vision: The pioneering of Non-Invasive Therapy. Mission: Respect Life in Therapy."
>
> — Shenzen PRO-HITU Medical CO, LTD

Clinical Device Manufacturers with Regulatory Approvals continued

Sonablate CORP

Devices

2 Total devices

2 Approved devices

Name	Status	Treatment guidance	Planning guidance
Sonablate	✚	US guidance	MR/US fusion
Sonatherm	✚	US guidance	US guidance

Approvals

2 Approved indications

6 Regions

25 Countries

46 Total approvals*

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	Canada	Health Canada, 2005
	North America	Costa Rica	Ministerio de Salud, 2005
	North America	Dominican Republic	MISPAS, 2005
	North America	United States	FDA, 2006
	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2005
	Europe	United Kingdom	MHRA, 2019
	Asia	China	NMPA, 2022
	Asia	Hong Kong	MDD, 2018
	Asia	India	CDSCO, 2011
	Asia	Israel	AMAR, 2018
	Asia	Japan	MHLW, 2001
	Asia	Macau	ISAF, 2020
	Asia	South Korea	MFDS, 2016
	Asia	Vietnam	DMEW, 2009

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on pp. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Sonablate CORP continued

Approvals continued

Indication	Region	Country	Agency and date
Urological continued			
Benign prostatic hyperplasia con't.	South America	Argentina	ANMAT, 2006
	South America	Colombia	INVIMA, 2015
	South America	Ecuador	ANRCVS, 2011
	South America	Trinidad and Tobago	Ministry of Health, 2012
	Oceania	Australia	TGA, 2005
Prostate cancer	North America	Bahamas	Ministry of Health, 2007
	North America	Barbados	Ministry of Health and Wellness, 2010
	North America	Canada	Health Canada, 2005
	North America	Costa Rica	Ministerio de Salud, 2005
	North America	Dominican Republic	MISPAS, 2005
	North America	United States	FDA, 2006
	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2005
	Europe	United Kingdom	MHRA, 2019
	Asia	China	NMPA, 2020
	Asia	Hong Kong	MDD, 2018
	Asia	India	CDSCO, 2011
	Asia	Israel	AMAR, 2018
	Asia	Macau	ISAF, 2020
	Asia	Pakistan	DRAP, 2015
	Asia	South Korea	MFDS, 2016
	Asia	Taiwan	FDA, 2020
	Asia	Vietnam	DMEW, 2009
	South America	Argentina	ANMAT, 2006
	South America	Colombia	INVIMA, 2015
	South America	Ecuador	ANRCVS, 2011
	South America	Trinidad and Tobago	Ministry of Health, 2012
	Oceania	Australia	TGA, 2005
	Africa	South Africa	MCC, 2007

Clinical Device Manufacturers with Regulatory Approvals continued

Sonablate CORP continued

Clinical research

6	3	5	15
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Colorectal tumors	1	1	2
Urological			
Prostate cancer	3	5	15
Women's health			
Cervical tumors	1	1	2
Endometrial tumors	1	1	1
Ovarian tumors	1	1	1
Vaginal tumors	1	1	1

> **Sonablate** is the leading innovator in minimally invasive ablation technology using high intensity focused ultrasound (HIFU). The Sonablate® prostate ablation system incorporates MRI/US image fusion for whole-gland, hemi, or focal procedures."
>
> — Sonablate CORP

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Echopulse	✚	US guidance	US guidance
SONOVEIN	✚	US guidance	Not used

Approvals

4	2	8	19
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Cardiovascular			
Varicose veins	Europe	Europe	CE Marking, 2019
	Asia	Hong Kong	MDD, 2021
	Asia	Singapore	HSA, 2019
Endocrine disorders			
Thyroid nodules	Europe	Europe	CE Marking, 2007
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Hong Kong	MDD, 2007
	Asia	Malaysia	MDA, 2019
	Asia	South Korea	MFDS, 2017
	Asia	Singapore	HSA, 2016
	Asia	Taiwan	FDA, 2019
	Asia	Thailand	FDA, 2019

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health			
Breast tumors, benign	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Hong Kong	MDD, 2012
	Asia	Malaysia	MDA, 2019
	Asia	Singapore	HSA, 2016
	Asia	South Korea	MFDS, 2017
	Asia	Taiwan	FDA, 2018
	Asia	Thailand	FDA, 2019

Clinical research

13	3	8	20
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Cardiovascular			
Varicose veins	3	4	4
Endocrine disorders			
Graves' disease	1	1	1
Thyroid nodules	1	3	9
Gastrointestinal			
Esophageal tumors	1	1	1
Gastric tumors	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA continued

Clinical research continued

Indication	Region	Country	Site
Miscellaneous			
Melanoma	1	1	1
Multiple tumors[1]	1	1	1
Pulmonary			
Lung cancer	1	1	1
Urological			
Acute tubular necrosis	1	1	1
Women's health			
Breast tumors, benign	2	2	5
Breast tumors, malignant	2	2	2
Cervical tumors	1	1	1
Ovarian tumors	1	1	1

> **Theraclion** believes that surgery, as we know it, is outdated. We replace it with a robotic treatment from outside the body using HIFU. Our leading-edge platforms are CE marked for varicose veins, breast fibroadenomas, and thyroid nodules."
>
> — Theraclion SA

1 Protocols inclusive of more than one indication

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA - Veterinary Medicine

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Echopulse	✚[1]	US guidance	US guidance

Clinical research

1	1	1	1
Indication	**Region**	**Country**	**Site**

Indication	Region	Country	Site
Feline			
Soft tissue cancer	1	1	1

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

1 Veterinary devices are not subject to regulatory review.

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Clinical Device Manufacturers with Regulatory Approvals continued

TOOsonix A/S

Devices

2	1		
Total devices	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
System ONE-M	✚	Image fusion	Visual guidance
System ONE-R	—	Image fusion	Visual guidance

Approvals

0	1	1	0
Approved indications[1]	**Region**	**Country**	**Total approvals***[1]

Indication	Region	Country	Agency and date
—	Europe	Europe	CE Marking, 2020

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.22.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 This device is currently approved for aesthetic indications, which are not tracked by the Foundation.

Clinical Device Manufacturers with Regulatory Approvals continued

TOOsonix s/A continued

Clinical research

4 Indications	2 Regions	5 Countries	6 Sites

Indication	Region	Country	Site
Miscellaneous			
Actinic keratosis	1	2	2
Basal cell carcinoma	1	2	3
Kaposi's sarcoma	1	1	1
Neurological			
Neurofibromatosis	2	2	2

> **TOOsonix** is a Danish medical device company committed to the field of dermatology. Our CE marked 20 MHz HIFU systems deliver noninvasive ultrasound to target areas in the human skin, destroying target tissue, while surrounding tissue remains unharmed."
>
> — TOOsonix A/S

Clinical Device Manufacturers with Regulatory Approvals continued

Wuxi Haiying Electronic Medical Systems CO, LTD

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
HY2900	✚	US guidance	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approval***

Indication	Region	Country	Agency and date
Women's health			
Uterine fibroids	Asia	China	NMPA, 2016

✚ Devices with regulatory approvals.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Approved Clinical Devices

NEW

Acoustic MedSystems

TheraVision	No image

Alpinion Medical Systems

Alpius 900	

As ambassadors for the technology to the wider public audience we often get asked what focused ultrasound medical devices look like. New in 2022, we are including a photographic index of focused ultrasound devices that are commercially available. The photos included were provided by the manufacturers. If there is no image, we were unable to secure a photo of the device by the publication date.

Approved Clinical Devices continued

Changjiangyuan Technology Development

NUTAS - Non-invasive Ultrasound Tumor Ablation System	No image
SUPER Knife - Focused Beam Therapy System	No image

Approved Clinical Devices continued

Chongqing Haifu Medical Technology

CZB	
CZF	No image

Approved Clinical Devices continued

Chongqing Haifu Medical Technology continued

JC	No image
JC200	

Approved Clinical Devices continued

EDAP TMS

Ablatherm

Focal One

Approved Clinical Devices continued

EpiSonica

ArcBLATE (ARC-100M)

EyeTechCare

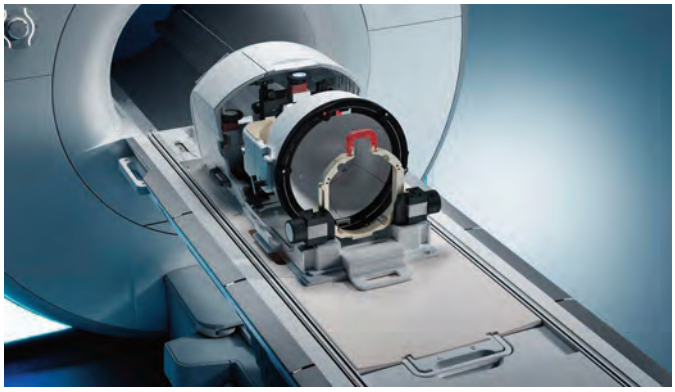
EyeOP1

Approved Clinical Devices continued

Insightec

Exablate Body

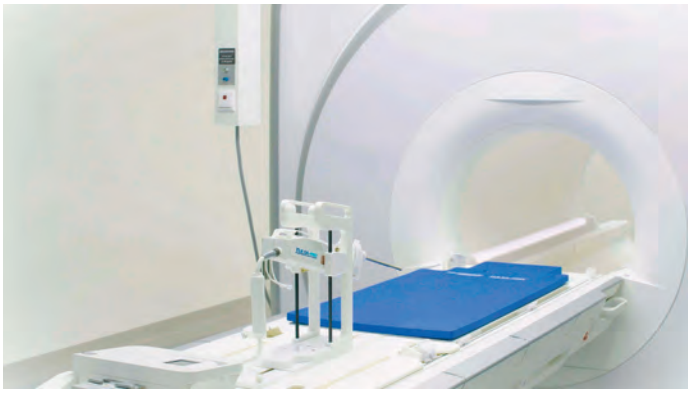
Exablate Neuro



Exablate Prostate

Approved Clinical Devices continued

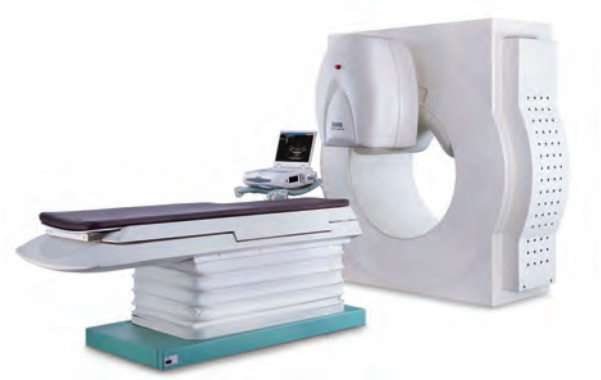
Profound Medical

Sonalleve	
TULSA-PRO	

Approved Clinical Devices continued

Shanghai A&S Science Technology Development

HIFUNIT9000



Shende Medical Equipment Technology

Aceso

Approved Clinical Devices continued

Shenzhen PRO-HITU Medical Technology

PRO2008

PRO300

PRO5G

Approved Clinical Devices continued

Sonablate

Sonablate	
Sonatherm	

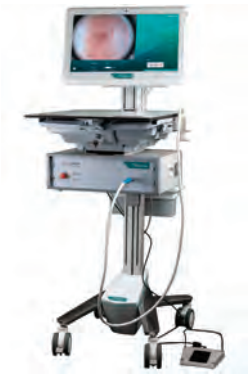
Approved Clinical Devices continued

Theraclion

Echopulse	
SONOVEIN	

Approved Clinical Devices continued

TOOsonix

System ONE-M	

Wuxi Haiying Electronic Medical Systems

HY2900	No image