October 3, 2017

EDAP Technomed, Inc.
Hugo Embert
CEO
5321 Industrial Oaks Blvd, Suite 110
Austin, TX 78735

Re: K172285
Trade/Device Name: Ablatherm® Fusion
Regulation Number: 21 CFR§ 876.4340
Regulation Name: High Intensity Ultrasound System for Prostate Tissue Ablation
Regulatory Class: II
Product Code: PLP
Dated: July 28, 2017
Received: July 28, 2017

Dear Hugo Embert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172285

Device Name
Ablatherm® Fusion

Indications for Use *(Describe)*
The Ablatherm® Fusion device is indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

EDAP Technomed, Inc

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USA

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Contact Person: Hugo EMBERT

Date Prepared: July 28, 2017

Proprietary Name: Ablatherm® Fusion

Common Name: High intensity ultrasound system for prostate tissue ablation

Regulatory Class: II

Regulation: 21 CFR 876.4340

Product Code: PLP

Predicate Devices

Ablatherm® Integrated Imaging (K153023), Sonablate® (K160942)

Intended Use:

The Ablatherm® Fusion device is indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue.

Device Description:

The device is a computer-controlled medical device intended to provide High Intensity Focused Ultrasound (also referred to as HIFU) to ablate prostate tissue. The system consists of the following main sub-assemblies: Therapy Control Module, Treatment Module, Endorectal Probe, and consumable Ablapak. HIFU is a unique process of delivering a large amount of heat energy to a confined space in a highly controlled manner. This energy heats the tissue to ablation levels while minimizing the effect on surrounding structures.

The ultrasound energy is delivered via an endorectal probe, which includes an imaging system. The ultrasound waves propagate through the rectal wall and are focused on a portion of the prostate, generating intense heat and causing the ablation of tissue within the targeted area. The process is then repeated in a stepwise fashion to destroy the targeted tissues within the prostate. The apex, sphincter and rectum are preserved while prostate tissues are ablated.

Technological characteristics

As previously cleared in the Ablatherm Integrated Imaging (K153023) predicate, the Ablatherm Fusion uses the same process and technology for delivering HIFU energy.

In addition, a dedicated software allowing elastic fusion between MR images /biopsies locations and ultrasound is integrated.

The purpose of this 510(k) submission is to add an optional feature that provides MRI images and/or biopsies positions fused with the system's live ultrasound imaging. This option is referred to as AblaFusion.

Performance Data

The following non-clinical testing was provided in support of this submission:

- Software Documentation
- Electrical safety & EMC test reports
- Fusion accuracy assessment through bench testing

Substantial Equivalence

	Ablatherm® Fusion	**Ablatherm® Integrated Imaging**	**Sonablate**
Manufacturer	EDAP TMS France	EDAP TMS France	SonaCare
510(k) No.	In progress	K153023	K160942
Product Code	PLP	PLP	PLP
Intended Use			
Indications for Use	Indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue.	Indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue.	Indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostatic tissue.
Prescription use	Yes	Yes	Yes
Minimally invasive	Yes	Yes	Yes
Outpatient procedures	Yes	Yes	Yes
Anesthesia required	Yes	Yes	Yes
Physician training	Yes	Yes	Yes

required				
General Description				
System Components	Therapy Control module, computers and peripherals. Treatment module, (patient support), endorectal probe, cooling unit, probe moment assembly and holder, movement detector, ultrasound scanner, Disposable accessories	Control module, computer and peripherals. Treatment module, (patient support), endorectal probe, cooling unit, probe moment assembly and holder, movement detector, ultrasound scanner, Disposable accessories	Control module, endorectal probe, computer and peripherals, cooling fluid, probe moment assembly and holder, Disposable accessories	
Patient position	right lateral decubitus	right lateral decubitus	lithotomy	
Performance characteristics				
Imaging modality for localization, treatment and control	Ultrasound	Ultrasound	Ultrasound	
Fusion of ultrasound with other imaging modalities (DICOM)	Yes	Not available	Yes	
Probe type	Curved array	Curved array	Linear Mechanical	
Imaging Frequency	7.5 MHz	7.5 MHz	4.0 MHz Nominal (3.5-8 MHz Range)	
Longitudinal Imaging frame rate (typical)	NA (Longitudinal image is reconstructed)	NA (Longitudinal image is reconstructed)	2 FPS	
Transverse Imaging frame rate (typical)	25 FPS	25 FPS	3 FPS	
Image size	8.0 x8.0 cm	8.0 x8.0 cm	4.5 x 6.25 cm	
Field of view	130°	130°	112°	
Ablation modality	HIFU	HIFU	HIFU	
Ablation Frequency	3.0 MHz	3.0 MHz	4.0 MHz	
Focal Distance	45 mm ± 2 mm	45 mm ± 2 mm	30 mm ± 1 mm	45 mm ± 2 mm

Probe length	60.9 mm	60.9 mm	58.7 mm
Probe diameter	38.4 mm	38.4 mm	33 mm
Probe neck diameter	19.5 mm	19.5 mm	18 mm
Management of protocols	Pre-set algorithm	Pre-set algorithm	Manual Adjustment

Conclusion

Software, technical and user manual changes do not constitute a new intended use, and any differences in technological characteristics do not raise new types of safety or effectiveness questions when compared to the predicate devices. Data is provided to assess the effects of the changes.

These data demonstrate that the device performs as intended and support a finding of substantial equivalence.