June 7, 2018

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

Re: K172721
Trade/Device Name: Focal One
Regulation Number: 21 CFR§ 876.4340
Regulation Name: High Intensity Ultrasound System for Prostate Tissue Ablation
Regulatory Class: II
Product Code: PLP
Dated: May 7, 2018
Received: May 7, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for 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

VI. INDICATIONS FOR USE STATEMENT

EDAP Technomed Inc's Indications for Use Statement for modified Focal One® is provided on the following page.

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)*

K172721

Device Name

FOCAL ONE

Indications for Use *(Describe)*

The Focal One 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) SUMMARY

EDAP Technomed, Inc
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USA
Phone: 512 832 7956
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Contact Person: Matthew Hull

Date Prepared: June 7, 2018

Proprietary Name: Focal One®
Common Name: High intensity ultrasound system for prostate tissue ablation
Regulatory Class: II
Regulation: 21 CFR 876.4340
Regulation Name: High intensity ultrasound system for prostate tissue ablation
Product Code: PLP
Predicate Device(s): Ablatherm Integrated Imaging (K153023), Sonablate (K160942)
Reference Device(s): Ablatherm Fusion (K172285)
Intended Use:
The Focal One® device is indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue.

Device Description:
The Focal One® is an evolution from the previous generation device, designed by EDAP: Ablatherm Integrated Imaging (K153023) and Ablatherm Fusion (K172285). The Focal One® consists of the Focal One® module with a software control system, an endorectal dynamic focusing probe, a leg holder, a set of single use disposables and a coupling liquid pouch.

The Focal One® module consists of a motorized and manual endorectal dynamic focusing probe positioning unit, a RF amplifier to power the transducer, a computer to control device operation, a cooling system to cool Ablasonic (coupling liquid) and built-in safety features. It also allows the user to control the treatment while providing different user interfaces: two dual touch-screens, mouse, keyboard and printer. The Focal One® energy is delivered via an endorectal dynamic focusing probe, which includes an imaging system. The high-energy 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 focal area. The process is then repeated in a stepwise fashion to destroy the targeted tissues within the prostate. The endorectal dynamic focusing probe is attached to a support, enabling movements in the longitudinal, transverse, vertical and angular directions, and in rotation. A coupling liquid pouch (Ablasonic®) included in the FocalPak disposable kit, attached to a stand, maintained at a controlled temperature flows continuously (via a peristaltic pump) into the balloon to preserve the rectal wall from heating associated with the treatment. The module is mounted on four multidirectional wheels allowing an easy positioning of the device in the treatment room.

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

- Sterilization and Shelf Life

- Biocompatibility
- Software Documentation
- Electrical Safety and Electromagnetic Compatibility
- IEC 60601-2-62: Medical electrical equipment Part 2 62 Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound HITU equipment.
- Bench Testing to assess the ablative performance (beam steering technology, acoustical parameters) of Focal One.
  Animal Studies on rabbit and pig models to confirm the ablative performance on the living tissue (dimensions, position of lesions and preservation of surrounding tissue).

Conformance to Recognized Standards
The Focal One® conforms to applicable sections of the following recognized consensus standards:

- ISO 10993-1, biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process.
- ISO 10993-5, Biological Evaluation Of Medical Devices: Test for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
- IEC 60601-1:2005- Corr 1:2006, Corr 2:2007, Medical Electrical Equipment - Part 1: General Requirements For Safety
- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Test
- IEC 62304: 2006/AC: 2006, Medical device software-Software life cycle processes.
- IEC 60601-2-62:1.0 2013-07, medical electrical equipment; part 2-62: particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (hitu) equipment.
- AAMI TIR12:2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturer
- AAMI TIR30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices,
- ANSI/AAMI ST81:2004/(R)2010 - Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 17664:2004 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Clinical Data
A clinical report summarizing data on subjects treated with the Focal One® High Intensity Focused Ultrasound (HIFU) device to provide evidence of the safety and effectiveness of the device for the ablation of prostate tissue has been provided in support of this submission. The EDAP data collection is a retrospective analysis of prospective clinical studies that demonstrates the efficacy of Focal One® HIFU supported by targeted volume and PSA reduction data and through prostate biopsies data.

This clinical report includes data from 100 subjects treated with Focal One® HIFU in four prospective clinical trials conducted in Europe. Despite the data having been collected in four separate studies, the patients in each trial had similar baseline and demographic characteristics, and all trials shared the same treatment approach (i.e., focal treatment of prostate tissue).. The studies were conducted primarily in sequential order over a period of 37 months which allowed for cumulative user group experience over time.

All subjects were treated with the commercial version of the device, demonstrating that the device performs as intended under anticipated conditions of use. Within the set of clinical trials presented, all selected

subjects were evaluated prior to the study procedure and then followed at 3 months, 6 months, 12 months, 18 months and 24 months post-HIFU.

Evidence of prostate tissue ablation was provided through post-HIFU evaluation of targeted volume, PSA reduction and stability as well as biopsy results. All adverse events were collected regardless of their relationship to the HIFU procedure. The majority of adverse events resolved with the exception of some cases of erectile dysfunction and urinary dysfunction.

Prostate volume reduction
Within the entire population of subjects considered in this analysis, after the focal HIFU treatment, the prostate volume, assessed by MRI changed significantly. For paired cases (subjects for which MRI data are available at baseline and measurement point) (78 subjects), it went from 49.8 ± 23.1 mL (median 44.0 mL) to 38.6 ± 25.5 mL (median 31.5 mL) ($p<0.001$). This represents a 22.7% reduction (95% confidence interval 17.6%; 27.8%).

PSA reduction Following Focal HIFU Procedure
PSA reduction is also presented as supporting evidence of ablation. Ninety-nine subjects presented some reduction of PSA during the follow-up phase.

PSA reductions from baseline to 6 and 12 months are presented in the table below. As shown in this table, the mean PSA reductions are statistically significant at both 6 months ($p<0.001$) and 12 months ($p<0.001$).

Variable	N	Mean	95% CI	Significance of reduction
PSA reduction at 6 months (ng/mL)	93	-3.7	- 4.3; - 3.1	< 0.001
Percentage PSA reduction at 6 months (%)	93	- 53.0	- 60.2; - 45.8	
PSA reduction at 12 months (ng/mL)	82	-3.7	- 4.2; - 3.1	< 0.001
Percentage PSA reduction at 12 months (%)	82	- 54.4	- 60.2; - 48.6	

The PSA nadir (lowest value measured during window of PSA assessment) is reached around 8 months after HIFU (mean nadir time achievement: 8.4 ± 6.3 months) with a median at 6.2. The mean PSA nadir is 2.2 ± 1.6 ng/ mL, with a median of 2.0 ng/mL.

In addition, in the analyzed population, the PSA velocity from first PSA assessment after HIFU procedure, to last not censured PSA measure performed, is – 0.57 ± 5.30 ng/mL/year (median 0.018 ng/mL/year) (see table below).

Variable	N	Mean	95% CI
PSA velocity ng/mL/year	96	- 0.57 ng/mL/year	- 1.65, 0.50

PSA reduction and subsequent stability provides additional evidence of prostate tissue ablation.

Histological evidence of tissue ablation
In the set of selected clinical trials presented, during the study, treatment outcome was monitored: a multiparametric MRI was performed, followed by a series of prostatic biopsies allowing the distinction between HIFU targeted area and not targeted area outcomes. Ninety-seven of the 100 subjects underwent biopsy. In the present data collection analysis, subjects who did not undergo control biopsies, in the duration of their follow-up in their respective study, were considered as positive.

This corresponds to a negative biopsy rate at the level of the targeted area of 63% (95% confidence interval 53.5%; 72.5%) (see table below).

Number of subjects	Negative Biopsy[(1)]	%	Positive Biopsy[(2)]	%
100	63	63.0	37	37.0

[(1)] Negative biopsy in targeted area. [(2)] Positive biopsy in targeted area or missing biopsy (3 in total) (noncompliance).

Based on the analysis of the post-HIFU prostate volume evolution, the PSA reduction and the control biopsies, results provide evidence of the effectiveness of the Focal One® device in ablating specifically prostate tissue.

The information below provides a detailed view of the adverse events reported during the European prospective clinical studies evaluating the focal treatment of the prostate using the Focal One which were submitted as evidence of the safety and effectiveness of the device for the ablation of prostate tissue. Given the retrospective nature of the 510(k) clinical data, a third party CRO audited the adverse event tabulations to verify the reliability and completeness of the data collection.

Adverse Event	**Any Occurrence # Events (% Subjects) (n=100)**
Any	237 (79%)
Erectile Dysfunction	45 (45%)
Urinary Tract Infection	39 (30%)
Urinary Retention	34 (27%)
Hematuria	19 (17%)
Miction disturbances	13 (13%)
Urinary Incontinence	13 (12%)
Prostate Infection	9 (8%)
Urinary Frequency	8 (8%)
Ejaculation Disorder	6 (6%)
Urinary Urgency	5 (5%)
Urinary Tract Obstruction	4 (4%)
Urinary Tract Pain	3 (2%)
Testicular Disorder	3 (2%)
Other [(1)]	35 (25%)

[(1)] includes Gastrointestinal disorders (4), Bladder tenesmen/catheter discomfort (3), Renal calculi (2), headache (2), hypotension (2),

Pelvic pain (2), rectal/anal pain (2), Allergic reaction (2), and other with 1 occurrence only throughout the whole 100 patients

Substantial Equivalence

The claim of substantial equivalence of the Focal One to the Ablatherm (K153023 and Sonablate (K160942) is based on the comparison of the indications and intended use, product design and technical characteristics, and performance characteristics.

	Focal One® – Subject Device	**Ablatherm®**	**Sonablate®**
Manufacturer	EDAP	EDAP	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 required	Yes	Yes	Yes
General Description			
System Components	Control module, Computer and peripherals, Endorectal probe, Cooling unit, Probe holder, Ultrasound scanner, Disposable accessories Probe movement assembly Movement detector,	Control module, Computer and peripherals. Endorectal probe, Cooling unit, Probe holder, Ultrasound scanner, Disposable accessories Probe moment assembly Movement detector, Treatment module (patient support),	Control module, Computer and peripherals Endorectal probe, Cooling unit, Probe holder, Ultrasound scanner 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	No	Yes	
Probe type	Curved Array	Curved array	Linear Mechanical	
Imaging Frequency	7 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	8x8cm	8x8cm	4.5 x 6.25 cm	
Field of view	140°	130°	112°	
Ablation modality	HIFU	HIFU	HIFU	
Ablation Frequency	3.0 MHz	3.0 MHz	4.0 MHz	
Focal Distance	60 mm ± 2 mm 32 – 67 mm	45 mm ± 2 mm	30 mm ± 1 mm	40 mm ± 2 mm
Probe length	60.9	60.9 mm	58.7 mm	
Probe diameter	38.4	38.4 mm	33 mm	
Probe neck diameter	25	19.5 mm	18 mm	
Management of protocols	Pre-set algorithm	Pre-set algorithm	Manual Adjustment	

*Note the Ablatherm Integrated Imaging 510(k) (K153023) listed 5 FPS as the typical Transverse Imaging frame rate. This was a typographical error. The typical Transverse Imaging frame rate should have been listed as 25 FPS.

The claim of substantial equivalence of the Focal One to the Ablatherm (K153023) and Sonablate (K160942) is also based on the comparison of clinical outcomes such as targeted volume as related to adverse events, PSA reductions from baseline, and biopsy results.

The claim of substantial equivalence for the image fusion function of Focal One "Fusion of ultrasound with other imaging modalities (DICOM)" references K172285 for the Ablatherm Fusion variant which was cleared for this feature.

Conclusion

Based on the indications and intended use, device design, performance and conformity with recognized consensus standards, as well as clinical data, the Focal One is substantially equivalent to the Ablatherm® Integrated Imaging (K153023) and the Sonablate® (K160942). The Focal One is as safe and effective as the predicate devices. Minor performance and technological differences between the Focal One and its predicate devices do not present new issues of safety and effectiveness when compared to the predicate devices. In vivo and in vitro testing, clinical testing and validation of the Focal One software confirm that the Focal One performs as intended. Thus, the Focal One is substantially equivalent.