



November 13, 2025

Edap Technomed, Inc.  
% Janice Hogan  
Partner  
Hogan Lovells US LLP  
1735 Market Street Suite 2300  
Philadelphia, Pennsylvania 19103

Re: K251910  
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: June 20, 2025  
Received: June 20, 2025

Dear Janice Hogan:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**MARK J. ANTONINO -S**

Mark J. Antonino, M.S.  
Assistant Director  
DHT3B: Division of Reproductive,  
Gynecology, and Urology Devices  
OHT3: Office of Gastrorenal, ObGyn,  
General Hospital, and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251910

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Please provide the device trade name(s).

?

Focal One®

Please provide your Indications for Use below.

?

The Focal One® is indicated for transrectal high-intensity focused ultrasound (HIFU) ablation of prostate tissue.

Please select the types of uses (select one or both, as applicable).

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

?

## 510(k) SUMMARY

**Applicant:** EDAP Technomed, Inc.  
5321 Industrial Oaks Blvd, Suite 110  
AUSTIN, TX 78735  
USA  
Phone: 512 832 7956  
Facsimile: 512 684 1313

**Contact Person:** Hugo EMBERT

**Date Prepared:** June 20, 2025

**Proprietary Name:** Focal One®

**Common Name:** High intensity ultrasound system for prostate tissue ablation

**Classification Name:** High intensity ultrasound system for prostate tissue ablation

**Regulatory Class:** II

**Regulation:** 21 CFR 876.4340

**Product Code:** PLP

**Predicate Device(s):** EDAP Technomed, Inc.'s Focal One® (K172721)

### 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 of Focal One® by EDAP as cleared in K172721. The Focal One® consists of the Focal One® module with a software control system, an endorectal dynamic focusing probe, a leg support, and a disposable set (FocalPak) including miscellaneous 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 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.

### Substantial Equivalence

The subject Focal One® device is an updated version of the previously cleared Focal One® (K172721) and is substantially equivalent to the Focal One® System cleared in K172721 (“predicate device”). The subject Focal One has the identical indications for use and principles of operation, and similar technological characteristics, as the previously cleared predicate. Minor differences in the technological characteristics between the subject device and the predicate do not raise different questions of safety or efficacy.

The ultrasound treatment by the therapeutic transducer remains unchanged compared to the cleared version. The main difference is the inclusion of a new imaging ultrasound to replace the imaging ultrasound in the cleared device. Notably, the modification to the imaging scanner has no impact on the overall device specification. Nor does it affect the user interface or the safety features of the device.

Other minor updates have been made, e.g., to replace obsolete components without altering specifications. None of the changes affect the treatment parameters or energy specifications.

	<b>Focal One® – Subject Device</b>	<b>Focal One® – Predicate Device</b>	<b>Comment</b>
Manufacturer	EDAP	EDAP	Same
510(k) No.		K172721	
Product Code	PLP	PLP	Same
<b>Intended Use</b>			
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.	Same
<b>Prescription use</b>	Yes	Yes	Same
<b>Minimally invasive</b>	Yes	Yes	Same
<b>Outpatient procedures</b>	Yes	Yes	Same
<b>Anesthesia required</b>	Yes	Yes	Same
<b>Physician training required</b>	Yes	Yes	Same
<b>General Description</b>			

	<b>Focal One® – Subject Device</b>	<b>Focal One® – Predicate Device</b>	<b>Comment</b>
<b>System Components</b>	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 movement assembly Movement detector,	Same
<b>Patient position</b>	right lateral decubitus	right lateral decubitus	Same
<b>Performance Characteristics</b>			
<b>Imaging modality for localization, treatment and control</b>	Ultrasound	Ultrasound	Same
<b>Fusion of ultrasound with other imaging modalities (DICOM)</b>	Yes	Yes	Same
<b>Probe type</b>	Curved Array	Curved Array	Same
<b>Imaging Frequency</b>	Between 6.6 and 7.7 MHz	Between 6.6 and 7.7 MHz	Same
<b>Longitudinal Imaging frame rate (typical)</b>	NA (Longitudinal image is reconstructed)	NA (Longitudinal image is reconstructed)	Same
<b>Transverse Imaging frame rate (typical)</b>	25 FPS	25 FPS	Same
<b>Image size</b>	8x8cm	8x8cm	Same
<b>Field of view</b>	144°	144°	Same
<b>Ablation modality</b>	HIFU	HIFU	Same
<b>Ablation Frequency</b>	3.0 MHz	3.0 MHz	Same

<b>Performance Characteristics</b>			
<b>Focal Distance</b>	60 mm ± 2 mm 32 – 67 mm	60 mm ± 2 mm 32 – 67 mm	Same
<b>Probe length (mm)</b>	60.9	60.9	Same
<b>Probe diameter (mm)</b>	38.4	38.4	Same
<b>Probe neck diameter (mm)</b>	25	25	Same
<b>Management of protocols</b>	Pre-set algorithm	Pre-set algorithm	Same

### **Non-Clinical Testing**

The following non-clinical testing was provided in support of this submission to demonstrate that the new system is equivalent to the cleared system:

- Biocompatibility Testing
- Reprocessing and Shelf Life Testing
- Electrical Safety and Electromagnetic Compatibility (EMC) Testing according to IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, and IEC 60601-2-62
- Software Documentation and Validation Testing
- Bench Testing to assess the new imaging ultrasound of Focal One.
- Human Factors Testing

### **Conclusion**

The Focal One and its predicate have the same indications for use and principles of operation, as well as similar technological characteristics. Minor differences in the technological characteristics, including the new ultrasound scanner, do not present different questions of safety or effectiveness as compared to the predicate devices. Performance testing demonstrate that the subject device is as safe and effective as its predicate devices. Thus, the Focal One is substantially equivalent to its predicate device.