October 30, 2023

Insightec, Ltd.
% Nadir Alikacem, Ph.D.
VP Regulated Clinical Affairs (US Agent)
Insightec, Inc.
4851 LBJ Freeway, Suite 400
Dallas, TX 75244

Re: K231378
Trade/Device Name: Exablate Prostate System
Regulation Number: 21 CFR§ 876.4340
Regulation Name: High Intensity Ultrasound System For Prostate Tissue Ablation
Regulatory Class: II
Product Code: PLP
Dated: September 28, 2023
Received: October 2, 2023

Dear Nadir Alikacem:

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231378

Device Name
Exablate Prostate System

Indications for Use *(Describe)*
The Exablate Prostate System is indicated for endorectal MR-Guided Focused Ultrasound (MRgFUS) ablation of Prostatic 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.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: May 10, 2023

Manufacturer:
Insightec, Ltd.
5 Nachum Heth St., PO Box 2059
Tirat Carmel 39120, Israel

Contact Person:
Inbal Ben-Tzvi
VP Regulatory Affairs
Phone: 972-54-244-5822
Fax: 972 4 813 1322

Device:

Trade Name:	Exablate Prostate System
Common name	Ultrasound System (MRgFUS)
Classification Name:	High Intensity Ultrasound System for Prostate Tissue Ablation
Classification Regulation:	21CFR §876.4340
Classification Panel:	Gastroenterology/Urology
Device Class:	Class II
Product Code:	PLP

Predicate Device:

Trade Name:	Exablate Prostate System
Manufacturer:	Insightec, Ltd.
510(k) Clearance:	K212150 (November 23, 2021)
Classification Name:	High intensity ultrasound system for prostate tissue ablation
Classification Regulation:	21CFR §876.4340
Classification Panel:	Gastroenterology/Urology
Device Class:	Class II
Product Code:	PLP

Device description: The Exablate 2100 / 2100V1 Type 3.0 Prostate System (Trademark Name: Exablate Prostate System) is a high intensity Magnetic Resonance ("MR") image- guided focused ultrasound (MRgFUS) system intended for endorectal use that delivers focused ultrasound energy into the prostate in a minimally invasive manner by utilizing an endorectal probe transducer.

The Exablate Prostate System combines a multiple-channel phased-array Focused Ultrasound (FUS) transducer probe and magnetic resonance imaging ("MRI") in a closed- loop treatment for the thermal procedure of Prostatic Tissue while monitoring the procedure in real time.

The Exablate Prostate System is designed to work in conjunction with FDA cleared 1.5T and 3.0T MRI scanners with phased array torso cardiac coils that is used for guidance and procedure monitoring and control feedback. The Exablate Prostate System is fully integrated with the MRI scanner used to provide MR images of the patient's anatomy and prepare an appropriate procedure plan. Measured tissue temperature changes provide feedback on the procedure dose in the targeted area and its surroundings, allowing real- time monitoring to achieve safe and effective outcomes.

The intended users for the Exablate Prostate System are trained and certified physicians and/or technicians (clinicians) who are seeking to offer patients an incisionless, focal, and MR guided and controlled prostate tissue ablation and have successfully completed the Insightec Exablate training to operate the device.

The Exablate Prostate System platform is intended to ablate prostatic tissue with focused ultrasound and operates in conjunction with FDA cleared compatible MRI scanners for the purposes of real time procedure planning, MR based guidance of the focused ultrasound energy to the target region, MR thermal imaging and ablation monitoring. The procedure effect of the Exablate Prostate System is achieved by accurately guiding the focus of the ultrasound energy to the target region. The energy is then repeatedly transmitted to the target until the desired outcome is achieved. The targeted area is defined based on MR images taken during the procedure, while patient is in procedure position.

The procedure is constantly monitored in a real-time closed-loop MR thermal feedback. Once the targeting is complete, the outcome is confirmed with adequate post-procedure MR imaging sequences.

The main purposes of this 510(k) submission include enhancements to the secondary water system operation and a reduction of treatment time.

Indications for Use: The Exablate Prostate System is indicated for endorectal MR-Guided Focused Ultrasound (MRgFUS) ablation of Prostatic Tissue.

Based on the information provided above, the Exablate Prostate System is considered substantially equivalent to the currently marketed predicate device in terms of Indications for Use.

Technological characteristics:

Comparisons with the predicate devise show the technological characteristics of the proposed Exablate Prostate System to be substantially equivalent to the predicate device. The proposed device is functionally identical to the predicate device.

Based on the information provided above, the Exablate Prostate System is considered substantially equivalent to the currently marketed predicate device in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

The following non-clinical studies were conducted on the Exablate Prostate System to support substantial equivalence to the predicate device:

- System level and Secondary Water System testing
- Techno-Clinical and Image Quality testing
- Usability testing
- Bioburden testing
- Shelf life testing of the treatment kit containing single use components

Software verification and validation testing were performed in accordance with the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" guidance documented issued on May 11, 2005, and IEC 62304.

Electrical safety, electromagnetic compatibility, and usability testing were tested by an accredited laboratory and demonstrated to be in accordance with the following standards:

- IEC 60601-1-2
- IEC 60601-2-62
- IEC 60601-1
- IEC 60601-1-6

Risk management was done in accordance with ISO 14971. All tests were used to support substantial equivalence of the subject device and demonstrate that the Exablate Prostate System:

- complies with the above mentioned international and FDA-recognized consensus standards and FDA guidance documents, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, Exablate Prostate System is substantially equivalent to the predicate device in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The Exablate Prostate System did not require clinical study because substantial equivalence to the currently marketed predicate device was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing

Conclusion:

Substantial equivalency was demonstrated by nonclinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that the Exablate Prostate System complies with the requirements specified in the international and FDA-recognized consensus standards.

Although there are differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety or effectiveness.

In conclusion, the Exablate Prostate System is substantially equivalent to the currently marketed predicate device K212150 in terms of indications for use, technological characteristics, and safety and effectiveness.