September 16, 2020

Profound Medical, Inc.
Goldy Singh
VP Product Management & Regulatory Affairs
2400 Skymark Avenue, Unit 6
Mississauga, Ontario L4W 5K5
Canada

Re: K202286
Trade/Device Name: TULSA-PRO® System
Regulation Number: 21 CFR§ 876.4340
Regulation Name: High Intensity Ultrasound System for Prostate Tissue Ablation
Regulatory Class: II
Product Code: PLP
Dated: August 13, 2020
Received: August 17, 2020

Dear Goldy Singh:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 J. Antonino, M.S.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202286

Device Name
TULSA-PRO® System

Indications for Use *(Describe)*

The TULSA-PRO® is indicated for transurethral ultrasound ablation (TULSA) 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.

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TULSA-PRO System
Special 510(k) application

510(k) Summary

I. General Information

- Applicant Name: Profound Medical Inc.
  2400 Skymark Avenue, Unit #6,
  Mississauga, ON L4W 5K5, Canada
  T: 647.476.1350 F: 647.847.3739

- Contact Name: Goldy Singh
  VP Regulatory Affairs & Product Management
  2400 Skymark Avenue, Unit #6,
  Mississauga, ON L4W 5K5, Canada
  Phone: 647.476.1350 × 403
  Fax: 647.847.3739
  Email: gsingh@profoundmedical.com

- Date of Submission: August 10, 2020

II. Device Identification

- Proprietary Name: TULSA-PRO® System
- Common Name: High Intensity Ultrasound System for Prostate Tissue Ablation
- Regulatory Class: Class II
- Regulation Number: 21 CFR 876.4340
- Regulation Name: High Intensity Ultrasound System for Prostate Tissue Ablation
- Product Code: PLP (High Intensity Ultrasound System for Prostate Ablation)

III. Predicate Device Information

- Predicate Device: TULSA-PRO System
- Common Name: High Intensity Ultrasound System for Prostate Tissue Ablation
- 510(k) Number: K191200

- Regulatory Class: Class II
- Regulation Number: 21 CFR 876.4340
- Regulation Name: High Intensity Ultrasound System for Prostate Tissue Ablation
- Product Code: PLP (High Intensity Ultrasound System for Prostate Tissue Ablation)
- Decision Date: August 15, 2019
- Manufacturer: Profound Medical Inc.

IV. Device Description

The Device description of the modified TULSA-PRO® system is as follows and it is identical to the cleared TULSA-PRO system.

The TULSA-PRO® system combines real-time Magnetic Resonance (MR) imaging and MR thermometry with transurethral directional ultrasound and closed-loop process control software to deliver precise thermal ablation of a customized volume of physician prescribed prostate tissue. The system consists of both hardware and software components.

Transurethral ultrasound ablation (TULSA) treatment ablates prostate tissue using in-bore real-time MRI treatment planning, monitoring, visualization, and active temperature feedback control. The closed-loop features of the TULSA-PRO® software use a real-time MRI interface to process MRI prostate temperature measurements, and communicate with the TULSA-PRO® hardware, thereby controlling frequency, power and rotation rate of ultrasound to ablate physician prescribed prostate tissue with a high degree of precision.

The physician inserts two catheters, one transurethral and another transrectal, into the patient before he is moved into the MR bore. The transurethral catheter consists of an Ultrasound Applicator (UA) which delivers energy from the urethra outwards into the prostate tissue, heating it to thermal coagulation. The transrectal catheter is an Endorectal Cooling Device (ECD) which does not emit any energy and cools the rectal wall adjacent to the prostate. Both catheters have fluid flowing inside throughout the treatment to thermally protect the urethra and rectum, in order to minimize the potential of any thermal damage to either the urinary or rectal pathways. The physician uses the

TULSA-PRO® console to robotically position the UA in the prostate and plan the treatment by contouring the prescribed tissue on real time high-resolution cross-sectional MR images of the prostate. These features provide the physician with the ability and the control to customize the treatment plan to minimize thermal impact to critical structures surrounding the prostate including the external urethral sphincter, rectum and neurovascular bundles. The treatment begins based upon the physician's instructions by enabling the software to initiate thermal ablation. The TULSA-PRO® closed-loop process control software reads real-time MR thermometry measurements and adjusts automatically and dynamically the frequency, power and rotation rate of ultrasound provided by each UA transducer, to deliver precise ablation of the prescribed prostate tissue. The software controls automated, continuous and robotic rotation of the transurethral UA by 360 degrees in sync with the process-controlled delivery of thermal heating to all the intended regions of the prostate. Following completion of the ablation process, the two catheters are removed from the natural orifices of the patients.

V. Intended Use:

The TULSA-PRO® is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue.

VI. Summary of Non-clinical testing

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

a. Bench Performance testing: Hardware design and development follows Profound Medical internal design control process. All design specifications for components of TULSA-PRO® system are verified either by design or by test and are traceable to a verification report or other document. All the performance testing performed on the subject device remains the same when compared with the cleared device K191200. The system as a whole is

validated in a simulated-use environment, which is a 3T MRI suite and 1.5T MRI suite with specified hardware and software parameters, identical to the system parameters of intended use.

b. Software Information: The Treatment Delivery Console (TDC) software version has been upgraded from V2.8 to V2.9. Software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

c. Electromagnetic Compatibility: Changes to PSIB have been tested to conform with Electromagnetic test requirements by Nationally Recognized Testing Laboratory

d. Packaging: There is no change in any sterile barrier packaging. The shipper boxes and foam insert sizes are modified for Positioning System (PS), Positioning System Interface Box (PSIB), Filter Box (FB) and Magnet Kit. The packaging meets the transit performance test requirements of ASTM D4169.

e. Biocompatibility: No change from K191200

f. Sterilization: No change from K191200

g. Electrical Safety testing: No change from K191200

h. Animal Studies: This premarket notification submission does not rely on the assessment of animal data to demonstrate substantial equivalence.

VII. Conformance to Recognized Standards

The TULSA-PRO® System complies with applicable sections of the following recognized consensus standards:

- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- ISO 14971 Medical devices – Application of risk management to medical devices
- ANSI/AAMI/IEC 62304 Medical device software – Software life cycle processes
- ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied
- ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating on a Near Passive Implants during Magnetic Resonance Imaging
- ISO\TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device

VIII. Clinical Data

The modifications of TULSA-PRO® System does not require additional clinical data to demonstrate substantial equivalence.

IX. Comparison to Predicate Device

The indication for use of the subject device remains unchanged from the predicate TULSA-PRO System (K191200).

Table1. Comparison of Predicate and Subject Device

	Predicate Device (TULSA-PRO System-K191200)	Subject Device (TULSA-PRO System)
Manufacturer	Profound Medical Inc.	Profound Medical Inc.
510(k) No.	K191200	Not assigned
Regulation Number	21 CFR 876.4340	Same
Product Code	PLP	Same
Indications for Use	TULSA-PRO® is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue.	Same
Prescription Use	Yes	Same
Non-surgical, Minimally invasive	Yes	Same
Outpatient procedures	Yes	Same
Anesthesia required	Yes	Same
Physician training required	Yes	Same
System Components	Main console containing electronics and programmable hardware (System Electronics unit) PC computer, LCD display, custom ablation delivery software (TDC unit) Water cooling circuit (System Cart, Fluid Circuit)	Same

	Transurethral Ultrasound Applicator (UA) Endorectal Cooling Device (ECD) Positioning System Disposable accessories	
Route of Energy Delivery	Trans-urethral	Same
Ablation modality	High Intensity Directional Ultrasound	Same
Imaging modality for localization, treatment and control	MRI	Same
Ablation Frequency	Dual Ablation Frequency: Low Frequency range: 4.1 – 4.5 MHz High Frequency range: 13.0 – 14.4 MHz	Same
Total acoustic power	4 W per element (low frequency) 2W per element (high frequency) Max (10 elements): 40W / 20W	Same
MRI Compatibility	3T MRI scanners	1.5T & 3T MRI Scanners

Conclusion:

The subject and predicate device share the same indications for use. Design differences between the subject and predicate device do not raise any new concerns or different questions of safety and effectiveness. The results of verification and validation activities demonstrate the substantial equivalence of the subject device to the predicate device.