September 20, 2023

Profound Medical, Inc.
Imen Ferchichi
Regulatory Affairs Lead
2400 Skymark Avenue, Unit 6
Mississauga, ON L4W 5K5
Canada

Re: K230692
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 11, 2023
Received: August 14, 2023

Dear Imen Ferchichi:

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 -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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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)*
K230692

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.

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PROFOUND

TULSA-PRO System

510(k) Summary

I. Submitter Information

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

- **Regulatory Contact:** Imen Ferchichi

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  Email: iferchichi@profoundmedical.com

- **Date Prepared:** **August 07, 2023**

II. Device Identification

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

III. Predicate & Reference Device Information

The original TULSA-PRO® System was cleared under K191200. Subsequent changes to the original system were cleared under K202286 and K211858.

Predicate Device	TULSA-PRO® System
510K Number	K191200
Decision Date	August 15, 2019
Manufacturer	Profound Medical Inc.

Reference Device	TULSA-PRO® System
510K Number	K202286
Decision Date	September 16, 2020
Manufacturer	Profound Medical Inc.

Reference Device	TULSA-PRO® System
510K Number	K211858
Decision Date	September 6, 2022
Manufacturer	Profound Medical Inc.

IV. Device Description

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 physician prescribed prostate tissue. The system consists of both hardware and software components. The subject device includes a modification to the device software that is described below. The hardware components and treatment workflow description are identical to the predicate device.

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 within 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.

The physician uses the TULSA-PRO console to robotically position the Ultrasound Applicator in the prostate and plan the treatment by contouring the prescribed tissue intended for ablation 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 starting the thermal ablation in the software. The TULSA-PRO closed-loop process control software reads real-time MR thermometry measurements and adjusts automatically and dynamically the frequency and power of ultrasound provided by each ultrasound transducer, and rotation rate of the Ultrasound

Applicator, to deliver precise ablation of the prescribed prostate tissue defined by the physician in the treatment plan.

Software Modification: An optional feature called Thermal Boost is available in the software during the treatment delivery phase of the treatment workflow. The Thermal Boost feature is useful when the prostate is large and the treatment radius is >15mm for any active ultrasound element. In such cases, heat may not reach the prostate boundary due to prostate size or if tissue perfusion is preventing the heat from reaching the target boundary. The physician has a choice to use the Thermal Boost feature on the corresponding ultrasound transducer. When this feature is turned on, the treatment boundary temperature can reach ≤63 degrees or ≤65 degrees depending on the treatment radius. Thermal Boost does not change the ablation plan prescribed by the physician. Whether Thermal Boost is turned on or off, the tissue heating and monitoring principle of operation of the TDC software do not change.

Following completion of the ablation process, the two catheters are removed from the natural orifices of the patient.

V. Intended Use

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

VI. Substantial Equivalence

The modified TULSA-PRO system is substantially equivalent to the TULSA-PRO that was submitted under K191200. The modified TULSA-PRO system has the same intended use and basic characteristics compared to the predicate device with respect to the functionality of the software. The Thermal Boost feature offers an improvement to the cleared device. The conclusions from all verification and validation data suggest that the modifications do not adversely impact the safety and effectiveness of the predicate device.

The substantial equivalence is demonstrated in Table 1.

Table 1. Substantial equivalence table

	Subject Device (TULSA-PRO System)	**Predicate Device (TULSA-PRO System)**	**Comparison Results**
Manufacturer	Profound Medical Inc.	Profound Medical Inc.	Same
510(k) No.	K230692	K191200	N/A
Regulation Number	21 CFR 876.4340	21 CFR 876.4340	Same
Product Code	PLP	PLP	Same
Indications for Use	The TULSA-PRO® is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue.	The TULSA-PRO® is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue.	Same
Prescription Use	Yes	Yes	Same
Non-surgical, minimally invasive	Yes	Yes	Same
Outpatient procedures	Yes	Yes	Same
Anesthesia required	Yes	Yes	Same
Physician training required	Yes	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) Transurethral Ultrasound Applicator (UA) Endorectal Cooling Device (ECD) Positioning System	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) Transurethral Ultrasound Applicator (UA) Endorectal Cooling Device (ECD) Positioning System	Same

	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
	Disposable accessories	Disposable accessories	
Patient position	Head-first supine	Head-first supine	Same
Route of Energy Delivery	Trans-urethral	Trans-urethral	Same
Prostate size limitation	Prostates up to 110cc	Prostates up to 110cc	Same
Ablation modality	High Intensity Directional Ultrasound	High Intensity Directional Ultrasound	Same
Imaging modality for localization, treatment and control	MRI	MRI	Same
Ablation Frequency	Dual Ablation Frequency: Low Frequency range: 4 – 4.8 MHz High Frequency range: 13.4 – 14.4 MHz	Dual Ablation Frequency: Low Frequency range: 4 – 4.8 MHz High Frequency range: 13.4 – 14.4 MHz	Same
Total acoustic power	4 W per element (low frequency) 2W per element (high frequency) Max (10 elements): 40W / 20W	4 W per element (low frequency) 2W per element (high frequency) Max (10 elements): 40W / 20W	Same
Probe type	Linear array	Linear array	Same
Ultrasound Transducer/Probe	Linear array of 10 planar rectangular ultrasound transducer elements with individually controlled frequency and power	Linear array of 10 planar rectangular ultrasound transducer elements with individually controlled frequency and power	Same
Probe Placement	Manual transurethral device insertion with guidewire. Probe attached to custom Positioning	Manual transurethral device insertion with guidewire. Probe attached to custom Positioning	Same

	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
	System arm mounted to MRI base plate (3-axis manual adjustment). Automated linear probe adjustment within urethra based on MR image guidance.	System arm mounted to MRI base plate (3-axis manual adjustment). Automated linear probe adjustment within urethra based on MR image guidance.	
Transducer Movement/Ablation volume	Automated device rotation using custom Positioning system. Transurethral probe rotates 360º to ablate prescribed prostate volume in one sweep.	Automated device rotation using custom Positioning system. Transurethral probe rotates 360º to ablate prescribed prostate volume in one sweep.	Same
Fusion of ultrasound with other imaging modalities (DICOM)	No	No	Same
Ultrasound Duty cycle	Continuous ultrasound delivery	Continuous ultrasound delivery	Same
Lesion Shape	5mm-wide directional beam (candle flame shape). Ten adjacent transducer elements produce overlapping heating pattern. Continuous volume of thermal ablation is delivered.	5mm-wide directional beam (candle flame shape). Ten adjacent transducer elements produce overlapping heating pattern. Continuous volume of thermal ablation is delivered.	Same
Ablation planning	Sagittal, Coronal and Axial planes	Sagittal, Coronal and Axial planes	Same
Longitudinal motion	6.4 cm	6.4 cm	Same
Management of protocols	Close-loop control algorithm	Close-loop control algorithm	Same

	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
Software Feature			
Thermal Boost	User-enabled feature, per ultrasound element, to use variable control temperature from 57°C to 65°C (not intended for the whole gland). This feature is optional and can be turned on to achieve the intended ablation when prostate radius is >15 mm.	Fixed control temperature at 57°C around the whole gland	**Modified:** The method and control of prostate tissue ablation remains the same. When prostate radius is > 15 mm and ultrasound heating is not reaching the desired boundary, this feature can be enabled by the user during treatment delivery in a user-selected region. The software verification and validation activities provided under VOL_16 and VOL_20 do not indicate change to the TULSA-PRO safety and effectiveness.

VII. Summary of Non-clinical testing

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

- Software verification and validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11,2005) to assess that the performance of the modified software is equivalent to the predicate device.
- Technical performance of the software with Thermal Boost enabled was compared to the predicate software during simulated prostate ablation in a tissue-mimicking gel phantom. Tissue temperature profiles were measured using MR thermometry, which is representative of clinical use. There were no significant differences in the temperature profile with respect to location of peak temperature or rate of change of temperature at the prostate boundary. Although Thermal Boost is not intended to be enabled for an entire prostate ablation

procedure, this scenario was evaluated as a worst case and specifications related to rectal cooling and treatment controller targeting statistics were met.

The following non-clinical testing that was provided in the original 510(k) remains applicable to the subject TULSA-PRO system, and is not included in this submission:

- Sterilization validation activities were performed in accordance with "ISO 11135 Second edition – Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices."
  - This standard is not applicable for this submission. There was no change to the sterilization specification.

- Biocompatibility testing was conducted in accordance with the 2020 FDA guidance document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"".
  - There is no change to the device materials or biocompatibility specification for the device with this submission.

- Electrical Safety and Electromagnetic Compatibility had been confirmed by Nationally Recognized Testing Laboratory.
  - There was no change to the device specification that impacts electrical safety or electromagnetic compatibility. There is no change to ultrasound power levels or frequency of device operation.

- Animal Studies – The animal testing that was provided in the original 510(k) remains applicable to support this 510(k) submission, as the principle of operation for heating tissue and monitoring the extent of ablation remains the same. The software verification and clinical data validation addresses all concerns of safety and effectiveness of the subject device.

VIII. Clinical Data

The predicate TULSA-PRO system (K191200) has previously been evaluated in prospective clinical studies, Phase I safety study (NCT01686958) and the Phase 2 pivotal study (herein referred to as the 'TACT' trial) (NCT02766543).

Clinical testing of the Subject Device:

Clinical performance of the Thermal Boost feature was evaluated to demonstrate that this feature does not raise further questions for safety and efficacy of the subject TULSA-PRO system when compared with the predicate device.

Clinical performance data were collected from 71 adult male patients treated with the commercially available TULSA-PRO system with Thermal Boost applied during the prostate ablation treatment, where needed. The area of prostate requiring Thermal Boost was determined by the treating physician. The device performance was documented and evaluated through adverse events assessed by the treating physician for a six-month period post-treatment, technical treatment performance statistics, and physician usability assessment of the feature.

The primary endpoint for determination of safety was rate of serious adverse events and adverse events with Thermal Boost compared to the predicate device. Patient follow-up of at least 6-month duration post-treatment was used to identify adverse events, using MedDRA for terminology and the Clavien-Dindo classification for grading. All events were captured regardless of causality. Adverse events reported with Thermal Boost are similar to those that were previously reported in the pivotal clinical data set for TULSA-PRO (epididymitis, urinary retention, pain/discomfort, urinary urgency, nocturia, urinary incontinence, ejaculation disorder, erectile dysfunction, urinary tract infection, and hematuria). There were no new complications observed in the Thermal Boost population.

The technical treatment performance was evaluated by comparing the physician-defined ablation plan to the temperature maps measured during ablation delivery by the software. These performance endpoints are used to assess the accuracy of the treatment controller and are the same as were evaluated for the predicate device clearance (K191200). With Thermal Boost enabled during treatment, the median (IQR) Dice Similarity Coefficient was 0.90 (0.88-0.92), Controller overshoot percentage was 6.4% (3.6%-10%), and controller undershoot percentage was 3.9% (1.7%-7.1%). All technical endpoints met the established performance criteria.

A usability questionnaire was administered to physicians who used the TUSLA-PRO System with the Thermal Boost feature. The purpose of this assessment was to evaluate that information provided to the users about the Thermal Boost feature was perceived,

understood, and supports correct use of the software feature. Responses from the usability questionnaire indicated that identification of the feature and training material was effective and there were no new use errors identified.

The results of the clinical study do not indicate any new risks or any concerns about safety or performance of the Thermal Boost feature of the TULSA-PRO software when compared to the predicate software.

IX. Conclusion

The modified TULSA-PRO software with the Thermal Boost feature does not raise any new concerns regarding device risk or different questions of safety and effectiveness. Software verification testing in a tissue mimicking phantom along with clinical data demonstrate that the device is as safe, as effective, and performs as well as the predicate device.