Profound Medical, Inc.
Golddy Kaur
VP Product Leader Sonalleve
2400 Skymark Avenue Unit #6
Mississauga, Ontario L4W 5K5
Canada

Re: K211858
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 3, 2022
Received: August 4, 2022

Dear Golddy Kaur:

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,

Reginald K. Avery, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211858

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.

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:** Nicole Baker

  Director Quality and Regulatory Affairs
  T: 647.476.1350 Ext.414
  M: 416.788.2253
  Email: nbaker@profoundmedical.com

- **Date Prepared:** September 1, 2022

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

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.

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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 transurethral ultrasound ablation (TULSA) treatment is delivered completely within the MR bore. A real-time MRI interface is used by closed-loop features of the TULSA-PRO system: real-time MRI prostate temperature measurements are processed by TULSA-PRO software which communicates with 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 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. The modified ECD component provides users with a rectal bubble removing feature, and is manufactured using a 3-D printed technology. 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 that was cleared under K191200 to robotically position the Ultrasound Applicator 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 cleared 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 required 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:

- Bench Performance testing was conducted to demonstrate that the TULSA-PRO system meets the requirements of the product design specification and performs in accordance with its intended use.
- 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"".

The following non-clinical testing 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.

- Electrical Safety and Electromagnetic Compatibility had been confirmed by Nationally Recognized Testing Laboratory. This standard is not applicable for this submission.
  - There was no change to the device specification that impact Electromagnetic disturbances.

- Animal Studies – Animal testing is not provided in support of this 510k submission, as bench testing and clinical testing addresses all concerns of substantial equivalence of the subject device.

Conformance to Recognized Standards

The changes to the TULSA-PRO System in this submission comply with applicable sections of the following recognized consensus standards:

- IEC 60601-1:2005/A1:2012 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- ISO 14971:2019 – Medical devices – Application of risk management to medical devices
- ISO 10993-1 Fifth edition 2018-08 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition 2009-06-01 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10 Third Edition 2010-08-01 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
- ISO 11737-1 Third edition 2018-01 – Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on product.
- ISO 15223-1 Third Edition 2016-11-01 – Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied
- ASTM F2052-15 – Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-11a – Standard Test Method for Measurement of Radio Frequency Induced Heating on a Near Passive Implants during Magnetic Resonance Imaging
- ASTM F2213-17 – Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

The following recognized consensus standards are applicable to the TULSA-PRO System, but these standards were not applied for the changes in this submission and there has been no change in conformance to these standards:

- IEC 60601-1-2 Edition 4.0 2014-02 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests –
    - This standard is not applicable for this submission. There was no change to the device specification that impact Electromagnetic disturbances.

- IEC 60601-1-6 Edition 3.1 2013-10 – General requirements for basic safety and essential performance – Collateral standard: Usability.
    - This standard is not applicable for this submission. There was no new risk introduced that related to usability.

- ANSI/AAMI 62366-1 Edition 1.0 2015-02 – Medical devices – Part 1: Application of usability engineering to medical devices.
    - This standard is not applicable for this submission. There was no new risk introduced that related to usability.

- IEC 60601-1-8 Edition 2.1 2012-11 – Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
    - This standard is not applicable for this submission. No alarm was changed under this submission.

- IEC 60601-1-10 Edition 1.1 2013-11 – Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers.
    - This standard is not applicable for this submission. There was no change to physiologic closed-loop under this submission.

- IEC 60601-2-62 Edition 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.
    - This standard is not applicable for this submission. There was no change to the device ultrasound specification.

- ANSI/AAMI/IEC 62304 Edition 1.1 2015-06 – Medical device software – Software life cycle processes
    - This standard is not applicable for this submission. There was no change to the medical device software.

- ISO 10993-4 Third edition 2017-04 – Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.

- This standard is not applicable for this submission. There was no change to the device specification related to parts interact with blood.

- ISO 10993-7 Second edition 2008-10-15 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
  - This standard is not applicable for this submission. There was no change to the sterilization specification.

- ISO 10993-11 Third edition 2017-09 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.
  - This standard is not applicable for this submission. There was no change to the device specification which impact toxicity.

- ISO 11135 Second edition 2014-07-15 – 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.

- ANSI/AAMI/ISO 11607-1:2006/(R) 2010 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging.
  - This standard is not applicable for this submission. There was no change to the sterile barrier specification.

- ANSI/AAMI/ISO 11607-2:2006/(R) 2010 - Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.
  - This standard is not applicable for this submission. There was no change to the sterile barrier specification.

- ANSI/AAMI/ISO 11737-2:2009/(R) 2014 – Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
  - This standard is not applicable for this submission. There was no change to the sterile barrier specification.

- EN ISO 14155 Second edition 2011-02-01 – Clinical investigation of medical devices for human subjects – Good clinical practice.
  - This standard is not applicable for this submission. There was no clinical study required for this notification submission.

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VII. Clinical Data

Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.

VIII. 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 ECD bubble removal feature.

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.	K211858	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	Main console containing electronics and programmable hardware (System Electronics unit) PC computer, LCD display, custom ablation	Same

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	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
	delivery software (TDC unit) Water cooling circuit (System Cart, Fluid Circuit) Transurethral Ultrasound Applicator (UA) Endorectal Cooling Device (ECD) Positioning System Disposable accessories	delivery software (TDC unit) Water cooling circuit (System Cart, Fluid Circuit) Transurethral Ultrasound Applicator (UA) Endorectal Cooling Device (ECD) Positioning System 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	Linear array of 10 planar rectangular ultrasound	Same

	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
	transducer elements with individually controlled frequency and power	transducer elements with individually controlled frequency and power	
Probe Placement	Manual transurethral device insertion with guidewire. Probe attached to custom Positioning System arm mounted to MRI base plate (3-axis manual adjustment). Automated linear probe adjustment within urethra based on MR image guidance.	Manual transurethral device insertion with guidewire. Probe attached to custom Positioning System arm mounted to MRI base plate (3-axis manual adjustment). Automated linear probe adjustment within urethra based on MR image guidance.	Same
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	5mm-wide directional beam (candle flame shape). Ten adjacent transducer elements produce overlapping heating pattern. Continuous volume	Same

	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
	of thermal ablation is delivered.	of thermal ablation is delivered.	
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
MR Scanner Compatibility	Added Siemens Vida 3T, Siemens Sola 1.5T, Philips Ingenia 1.5T, and Philips Ingenia Evolution 1.5T	Siemens: Skyra 3T, Prisma 3T, Aera 1.5T Philips: Achieva 3T, Ingenia 3T, Ingenia Elition 3T, Ingenuity PET-MR 3T	Modified: increase the number of MR scanners that can be used with the TULSA-PRO system.
Feature	**Endorectal Cooling Device (ECD)**		
Bubble Removal	Additional two gel lubricant channels intended for the user to manually remove bubbles by suction.	Fluid lines for circulation of cooling fluid to cool the rectal tissue adjacent to the prostate.	**Modified:** provide the user with a means of bubble removal that is more deterministic than previous methods. Bench testing was performed to verify and validate the ECD performance and safety and effectiveness of the TULSA PRO system
Manufacturing Process of ECD Body	3D-printing technology	Injection molding technology	**Modified:** provide holes on the ECD body surface to inject and extract lubricant gel to remove trapped bubbles on the ECD surface by negative pressure. Bench testing was performed to verify and validate the ECD performance and safety and effectiveness of the TULSA PRO system
Material	BioMed Clear Resin	ABS LUSTRAN 348 Polyester (PET)	**Modified:** Both materials meet the

	Subject Device (TULSA-PRO System)	Predicate Device (TULSA-PRO System)	Comparison Results
			Biocompatibility criteria for the intended use of ECD.

IX. Conclusion

The modified features of the TULSA-PRO Endorectal Cooling Device (ECD) do not raise any new concerns or different questions of safety and effectiveness. The verification and validation tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.