August 15, 2019

Profound Medical Inc.
Goldy Singh
VP, Clinical and Regulatory Affairs
2400 Skymark Avenue, Unit #6
Mississauga Ontario L4W5K5
CANADA

Re: K191200
Trade/Device Name: TULSA-PRO System
Regulation Number: 21 CFR 876.4340
Regulation Name: High Intensity Ultrasound System for Prostate Tissue Ablation
Regulatory Class: Class II
Product Code: PLP
Dated: July 16, 2019
Received: July 17, 2019

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,

for Glenn B. Bell, Ph.D.
Assistant Division 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)*
K191200

Device Name
TULSA-PRO SYSTEM

Indications for Use *(Describe)*
The TULSA-PRO System 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 MEDICAL Inc.

K191200 Traditional 510(k) – TULSA-PRO System

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

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

- **Date Prepared:** 2 Aug 2019

II. Device Identification

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

PROFOUND MEDICAL Inc.

III. Predicate Device Information

Predicate Device	Ablatherm Integrated Imaging
510(k) Number	K153023
Decision Date	Nov 6, 2015
Manufacturer	EDAP Technomed, 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 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® System 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 for the TULSA-PRO System to demonstrate that the system meets the requirements of the product design specification and performs in accordance with its intended use.
- Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a Risk Management Process.
- Software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”
- 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.”
- Electrical Safety and Electromagnetic Compatibility have been confirmed by a Nationally Recognized Testing Laboratory.
- Animal Studies – Animal studies were conducted on a canine prostate model.

PROFOUND MEDICAL Inc.

VII. Conformance to Recognized Standards

The TULSA-PRO System complies 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
- 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
- IEC 60601-1-6 Edition 3.1 2013-10 – General requirements for basic safety and essential performance – Collateral standard: Usability
- ANSI/AAMI 62366-1 Edition 1.0 2015-02 – Medical devices – Part 1: Application of usability engineering to medical devices
- 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
- 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
- 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
- ISO 14971:2012 – Medical devices – Application of risk management to medical devices
- ANSI/AAMI/IEC 62304 Edition 1.1 2015-06 – Medical device software – Software life cycle processes
- ISO 10993-1 Fifth edition 2018-08 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-4 Third edition 2017-04 – Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5 Third edition 2009-06-01 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7 Second edition 2008-10-15 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10 Third Edition 2010-08-01 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

- ISO 10993-11 Third edition 2017-09 – Biological evaluation of medical devices – Part 11: Tests for systemic 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
- ANSI/AAMI/ISO 11607-1:2006/(R) 2010 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging
- ANSI/AAMI/ISO 11607-2:2006/(R) 2010 - Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11737-1 Third edition 2018-01 – Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on product
- 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
- EN ISO 14155 Second edition 2011-02-01 – Clinical investigation of medical devices for human subjects – Good clinical practice
- 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

VIII. Clinical Data

The TULSA-PRO has been evaluated in prospective clinical trials, including the TACT Pivotal Study which was designed to determine the safety and effectiveness of the device according to the proposed intended use. Between September 2016 and February 2018, the TACT study enrolled 115 patients across the United States, Canada and Europe with biopsy-proven, organ-confined prostate cancer (67.0% and 33.0% of subjects had NCCN intermediate and low risk disease, respectively). All patients received primary treatment of whole-gland prostate ablation with sparing of the urethra and urinary sphincter. The median age of enrolled patients was 65

years, with targeted prostate volume of 40 cc and ultrasound treatment delivery time of 51 minutes. A median of 97.6% of the prescribed prostate volume was heated to an ablative thermal dose with spatial ablation precision of ±1.4 mm measured on MRI thermometry during treatment.

The primary efficacy endpoint of TACT was the proportion of patients achieving a post-treatment PSA reduction ≥ 75% of their pre-treatment baseline value. The primary safety endpoint was the frequency and severity of all adverse events graded according to the Common Terminology Criteria for Adverse Events (CTCAE). Secondary endpoints included prostate volume reduction, proportion of patients with negative biopsy, patient reported changes in quality of life (erectile, urinary and bowel function), and evaluation of multiparametric prostate MRI. Primary and secondary endpoints were assessed at 12 months after TULSA-PRO treatment, with per-protocol follow-up continuing to 5 years.

The TULSA-PRO device used to collect clinical data was developed and manufactured in accordance with requirements of ISO 13485 compliant Quality Management System. The prospective clinical studies were conducted in accordance with 21 CFR 812 regulations.

Safety: Adverse Events

All Adverse Events (AE) were documented during the TACT study regardless of their attribution to the TULSA-PRO procedure. All AE's were evaluated according to the Common Terminology Criteria for Adverse Events (CTCAE) developed by the NCI and were standardized to medical terminology using the Medical Dictionary for Regulatory Activities (MedDRA). Table 1 summarizes all AE observed during the TACT pivotal study through to the 12-month visit, regardless of severity or relation to the TULSA-PRO device or procedure. To 12 months, there was no rectal injury or fistula, and no severe urinary incontinence or erectile dysfunction. There were no Grade 4 or higher AE related or possibly related (attributable) to TULSA-PRO. There was one unrelated Grade 4 event of coronary artery disease resolved with a triple coronary artery bypass. There were 12 attributable Grade 3 AE in 9 patients (7.8%), all resolved by the 12 month follow-up. An additional 10 unrelated Grade 3 events occurred in 7 subjects, of which two were ongoing at 12 months: an upper GI bleed caused by esophageal adenocarcinoma which was resolving as of 12 months, and unrelated pelvic pain caused by a urinary stone which resolved after the 12 month visit.

The majority of attributable events were acute Grade 1 and 2 (occurring and resolving within 3 months of treatment), related to the genitourinary system.

Urethral stenosis occurred in 3 subjects (one Grade 2 and two Grade 3, all resolved). Urinary tract infections were common and resolved with oral antibiotics in nearly all affected patients. Urinary retention occurred in 9 attributable Grade 2 events (7% of patients) and 2 attributable Grade 3 events (1.7%), all resolved with medication and prolonged catheterization up to a maximum of less than 3 months. Attributable gastrointestinal AE were limited to acute Grade 1 events and 7 acute Grade 2 events: pain/discomfort (3.5% of subjects), nausea (1.7%), and constipation (0.9%), all of which resolved within one month and could potentially be attributed to anesthesia or GI anti-spasmodic medication.

Erectile dysfunction and urinary incontinence are common events after prostate therapies. Erectile dysfunction after TULSA-PRO in the TACT study was expected due to the whole-gland nature of the ablation. Of the 52 patients (45.2%) with some erectile dysfunction immediately after TULSA-PRO treatment, 49 (42.6%) were assessed by the study investigators as attributable to TULSA-PRO, of which 41 (35.7%) were ongoing at the 12-month follow-visit: 14 patients (12.2%) had mild erectile dysfunction (Grade 1, intervention not indicated), 27 patients (23.5%) had moderate erectile dysfunction (Grade 2, intervention such as medication indicated), and no patient (0%) had severe erectile dysfunction (Grade 3, intervention such as medication not helpful) or permanent disability.

Of the 28 patients (24.3%) with some urinary incontinence immediately after TULSA-PRO treatment, 26 (22.6%) were assessed by the study investigators as attributable to TULSA-PRO, of which 12 (10.4%) were ongoing at the 12-month follow-visit: 9 patients (7.8%) had mild urinary incontinence (Grade 1, occasional, pads not indicated), 3 patients (2.6%) had moderate urinary incontinence (Grade 2, spontaneous, pads indicated), and no patient (0%) had severe urinary incontinence (Grade 3, operative intervention indicated) or permanent disability.

Ongoing attributable moderate (Grade 2) AE at 12 months included ejaculatory disorder (retrograde ejaculation, 2.6% of subjects), weak urinary stream (2.6%), urinary tract infection (1.7%), and disrupted urethra (0.9%, identified on cystoscopy).

Table 1: Summary of all adverse events in TACT. Number of patients with AE, any occurrence and ongoing at the 12-month follow-up visit. Multiple AE of the same name are listed once per patient using highest attributable grade, sorted by frequency.

Adverse Event (AE)	Any occurrence, regardless of attribution # Subjects (%) (n=115)	Subset of AE attributable to TULSA-PRO # Subjects (%) (n=115)
Total	109 (94.8 %)	101 (87.8 %)
Erectile dysfunction	52 (45.2 %)	49 (42.6 %)
Haematuria	48 (41.7 %)	42 (36.5 %)
Urinary tract infection	42 (36.5 %)	32 (27.8 %)
Dysuria	29 (25.2 %)	21 (18.3 %)
Urinary incontinence	28 (24.3 %)	26 (22.6 %)

Adverse Event (AE)	Any occurrence, regardless of attribution # Subjects (%) (n=115)	Subset of AE attributable to TULSA-PRO # Subjects (%) (n=115)
Pain/discomfort (pelvic/genital/treatment area)	27 (23.5 %)	25 (21.7 %)
Oedema (testicular, scrotal, penile)	27 (23.5 %)	24 (20.9 %)
Urinary urgency	26 (22.6 %)	25 (21.7 %)
Catheter site pain/inflammation	20 (17.4 %)	7 (6.1 %)
Pain/discomfort (abdominal/anorectal)	17 (14.8 %)	14 (12.2 %)
Urinary frequency	16 (13.9 %)	16 (13.9 %)
Bladder spasm	14 (12.2 %)	12 (10.4 %)
Ejaculation disorder	14 (12.2 %)	14 (12.2 %)
Non-descriptive LUTS	14 (12.2 %)	10 (8.7 %)
Urinary retention	13 (11.3 %)	10 (8.7 %)
Urethral bleeding	13 (11.3 %)	13 (11.3 %)
Pain/discomfort (hip/back)	12 (10.4 %)	9 (7.8 %)
Urethral discharge	11 (9.6 %)	11 (9.6 %)
Weak urinary stream	11 (9.6 %)	11 (9.6 %)
Pain/discomfort (bladder/urinary tract)	10 (8.7 %)	9 (7.8 %)
Fatigue	9 (7.8 %)	3 (2.6 %)
Hypotension	8 (7 %)	
Nausea	8 (7 %)	2 (1.7 %)
Epididymitis	7 (6.1 %)	7 (6.1 %)
Headache	7 (6.1 %)	2 (1.7 %)
Debris in urine	5 (4.3 %)	5 (4.3 %)
Orchitis	5 (4.3 %)	2 (1.7 %)
Constipation	4 (3.5 %)	2 (1.7 %)
Dyspepsia	4 (3.5 %)	
Fever	4 (3.5 %)	3 (2.6 %)
Hypertension	4 (3.5 %)	
Nocturia	4 (3.5 %)	3 (2.6 %)
Procedural hypotension	4 (3.5 %)	
Libido decreased	4 (3.5 %)	
Inguinal hernia	3 (2.6 %)	
Urethral stenosis	3 (2.6 %)	3 (2.6 %)
Calculus urinary	2 (1.7 %)	1 (0.9 %)
Hydronephrosis	2 (1.7 %)	1 (0.9 %)
Anaemia	1 (0.9 %)	
Syncope	1 (0.9 %)	
Upper gastrointestinal haemorrhage	1 (0.9 %)	
Urinoma	1 (0.9 %)	1 (0.9 %)
Urosepsis	1 (0.9 %)	
Deep vein thrombosis	1 (0.9 %)	1 (0.9 %)
Diverticulitis	1 (0.9 %)	
Ileus	1 (0.9 %)	
Other*	95 (82.6 %)	41 (35.7 %)

* Includes all non-serious Grade ≤ 2 events with occurrence in < 3% of all patients

Effectiveness: Prostate Volume Reduction, PSA Reduction and Prostate Biopsy at 12 months

Evidence of effective prostate tissue ablation is provided through Prostate Volume Reduction, PSA Reduction and Prostate Biopsy at 12 months.

Prostate Volume Reduction

Prostate volume reduction was measured in the TACT study demonstrating effective ablation of the prescribed prostate volume. As per protocol, the TACT study employed a central radiology core lab to measure prostate volume prior to and after treatment with TULSA-PRO, providing consistent methodology and reducing inter-observer variability. In the TACT study, 106 of the 115 patients had MR image data prior to and after TULSA (at 12 months) that were available and readable by the central radiology core lab. Based on the per-protocol assessment from a central radiology core lab, the median (IQR) perfused prostate volume of patients in TACT decreased 91.4% from 37.3 (27.2 – 47.6) cc pre-treatment to 2.8 (1.7 – 4.7) cc at 12 months on MRI. The mean and 95% confidence interval of the prostate volume reduction was 89% (87 – 91%). Given the treatment intent of whole-gland ablation with sparing of the urethra and urinary sphincter, the prostate volume reduction measurements demonstrate that the TULSA-PRO achieved effective prostate tissue ablation.

PSA Reduction

PSA reduction and stability provide additional evidence of effective prostate tissue ablation. Reduction of PSA was observed in all patients at nadir and at 12 months. Primary endpoint of PSA reduction ≥75% was achieved in 110 of 115 (96%) patients. Mean (95% confidence interval) PSA reduction to nadir was 92% (90 – 94%). Median (IQR) PSA reduction was 95% (91 – 98%) to nadir of 0.34 (0.12 – 0.56) ng/ml. Median (IQR) PSA decreased from 6.26 (4.65 – 7.95) ng/ml to 0.53 (0.30 – 1.19) ng/ml at 1 month, remaining stable to 0.53 (0.28 – 1.25) ng/ml at 12 months.

Prostate Biopsy at 12 months

Negative prostate biopsy outcomes provide additional evidence of effective prostate tissue ablation. Prostate histological response was evaluated through 10-core prostate biopsy at 12 months, providing high sampling density of the prostate due to the significant volume reduction after TULSA-PRO treatment. Of 115 patients enrolled in the study, 4 (3.5%) did not undergo follow-up biopsy, all due to patient refusal.

Using an intent-to-treat analysis (ITT), of 115 patients enrolled in the study, 72 (63%) had a complete histological response with no evidence of any cancer (95% confidence interval: 54 – 71%). For this ITT analysis, the 4 patients who refused follow-up biopsy were considered “positive”.

This data is consistent with the prescribed treatment plan, supports the substantial equivalence of the TULSA-PRO to its predicate, and demonstrates safety and effectiveness of the device for ablation of prostate tissue.

IX. Substantial Equivalence

The Ablatherm Integrated Imaging has been selected as a predicate device to establish substantial equivalence to TULSA-PRO. Both the subject and predicate devices are High Intensity Therapeutic Ultrasound devices and are indicated for the ablation of prostate tissue. Both devices are intended for use by physicians who have completed mandatory training for safe operation of the devices. Both the subject and predicate devices are intended for prescription use and are performed as minimally invasive procedures.

Although there are differences in technological features that could impact safety or effectiveness, the safety and effectiveness of the TULSA-PRO have been demonstrated through assessment of clinical studies. The substantial equivalence is demonstrated in the Table 2.

Table 2. Substantial equivalence table

	Subject Device (TULSA-PRO System)	**Predicate Device (Ablatherm Integrated Imaging)**
Manufacturer	Profound Medical Inc.	EDAP Technomed, Inc.
510(k) No.	Not yet assigned	K153023
Regulation Number	21 CFR 876.4340	21 CFR 876.4340
Product Code	PLP	PLP
Indications for Use	TULSA-PRO® is indicated for thermal ablation of prescribed prostate tissue, benign and malignant, using transurethral ultrasound ablation (TULSA) with in-bore real-time MRI treatment planning, monitoring, visualization, thermal dosimetry, and active temperature feedback control of thermal treatment.	The Ablatherm Integrated Imaging device is indicated for transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue.
Prescription Use	Yes	Yes
Non-surgical, Minimally invasive	Yes	Yes
Outpatient procedures	Yes	Yes
Anesthesia required	Yes	Yes
Physician training required	Yes	Yes
System Components	Main console containing electronics and	Control module, computer and peripherals. Treatment

PROFOUND MEDICAL Inc.

K191200 Traditional 510(k) – TULSA-PRO System

	Subject Device (TULSA-PRO System)	Predicate Device (Ablatherm Integrated Imaging)
	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 Disposable accessories	module, (patient support), endorectal probe, cooling unit, probe moment assembly and holder, movement detector, ultrasound scanner, Disposable accessories
Patient position	Head-first supine	Right lateral decubitus
Route of Energy Delivery	Trans-urethral	Trans-rectal
Prostate size limitation	Prostates up to 110cc	Not available
Ablation modality	High Intensity Directional Ultrasound	High Intensity Focused Ultrasound
Imaging modality for localization, treatment and control	MRI	Ultrasound
Ablation Frequency	Dual Ablation Frequency: Low Frequency range: 4 – 4.8 MHz High Frequency range: 13.4 – 14.4 MHz	3.0 MHz
Total acoustic power	4 W per element (low frequency) 2W per element (high frequency) Max (10 elements): 40W / 20W	35-48 W according lesion length (19 to 24 mm)
Probe type	Linear array	Curved array
Ultrasound Transducer/Probe	Linear array of 10 planar rectangular ultrasound transducer elements with individually controlled frequency and power	Transducer array with choice of power and focal length

PROFOUND MEDICAL Inc.

K191200 Traditional 510(k) – TULSA-PRO System

	Subject Device (TULSA-PRO System)	**Predicate Device (Ablatherm Integrated Imaging)**
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.	The endorectal probe is attached to the probe movement assembly on the treatment module, and is inserted into the patient's rectum during treatment.
Transducer Movement/Ablation volume	Automated device rotation using custom Positioning system. Transurethral probe rotates 360^{o} to ablate prescribed prostate volume in one sweep.	Not available
Fusion of ultrasound with other imaging modalities (DICOM)	No	No
Ultrasound Duty cycle	Continuous ultrasound delivery	6 seconds "on" and 4 seconds "off"
Lesion Shape	5mm-wide directional beam (candle flame shape). Ten adjacent transducer elements produce overlapping heating pattern. Continuous volume of thermal ablation is delivered.	Multiple discrete volumes of thermal ablation are delivered
Ablation planning	Sagittal, Coronal and Axial planes	In transverse and longitudinal planes
Longitudinal motion	6.4 cm	8.0 cm max length scanning
Management of protocols	Close-loop control algorithm	Pre-set algorithm