August 30, 2023

PROCEPT BioRobotics Corporation
Sara Muddell
Senior Director, Global Regulatory Affairs
900 Island Drive, Suite 101
Redwood City, CA 94065

Re: K231024
Trade/Device Name: AQUABEAM® Robotic System
Regulation Number: 21 CFR§ 876.4350
Regulation Name: Fluid Jet System For Prostate Tissue Removal
Regulatory Class: II
Product Code: PZP
Dated: July 31, 2023
Received: August 1, 2023

Dear Sara Muddell:

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
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)*
K231024

Device Name
AQUABEAM® Robotic System

Indications for Use *(Describe)*
The AQUABEAM Robotic System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia.

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

1. Submitter

PROCEPT BioRobotics Corporation
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Contact:
Sara Muddell
Senior Director, Global Regulatory Affairs
Telephone: (650) 232-7217
Email: s.muddell@procept-biorobotics.com

Date Prepared: April 10, 2023

2. Device

Trade Name:	AQUABEAM® Robotic System
Common Name:	Fluid jet system for prostate tissue removal
Classification Name:	Fluid jet system for prostate tissue removal
Regulation Number:	21 CFR 876. 4350
Product Code:	PZP
Classification:	Class II

3. Predicate Devices

Trade Name	AQUABEAM® System	AQUABEAM® Robotic System
Clearance Number	DEN170024	K212835
Product Code	PZP	PZP

4. Device Description

The AQUABEAM® Robotic System is intended for use in patients suffering from lower urinary tract symptoms (LUTS) resulting from benign prostatic hyperplasia (BPH). The AQUABEAM Robotic System is designed for resecting of prostate tissue during minimally invasive surgical procedures. The AQUABEAM Handpiece and AQUABEAM Scope are inserted via transurethral approach and advanced into the prostatic urethra.

The AQUABEAM Robotic System is designed to utilize a high-velocity sterile saline waterjet as the cutting medium which is projected through a nozzle positioned within the prostatic urethra. The nozzle assembly motion is driven by a motor system, controlled by the user. The pressure is generated by a high-pressure pump system controlled by the AQUABEAM Console. The user is allowed to adjust the desired flow rates manually. All functions are displayed on the AQUABEAM Conformal Planning Unit. Pre-condition parameters are set on the AQUABEAM Conformal Planning Unit before operation.

The AQUABEAM Robotic System, consists of the following nine components:

- AQUABEAM Console
- AQUABEAM Motorpack
- AQUABEAM Foot pedal
- AQUABEAM Conformal Planning Unit
- AQUABEAM Roll Stand
- AQUABEAM Handpiece Articulating Arm
- AQUABEAM TRUS Articulating Arm
- AQUABEAM Handpiece
- AQUABEAM Scope

5. Indications for Use

The AQUABEAM Robotic System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia.

The intended use of the subject device is identical to the intended use of the predicate device.

6. Technological Characteristics

This 510(k) is submitted for changes to the device labeling. The device's technological characteristics are unchanged relative to the predicate device.

7. Device Comparison

The AQUABEAM Robotic System subject device includes the following changes to the device labeling:

Characteristic	Subject Device	Predicate Device
Contraindications	Do not use the AQUABEAM Robotic System in patients who do not meet the indication for the system's intended use. In addition, do not use the system in patients with: • Active urinary tract or systemic infection • Inability to safely stop anticoagulant or antiplatelet agents perioperatively	Do not use the AQUABEAM Robotic System in patients who do not meet the indication for the system's intended use. In addition, do not use the system in patients with: • Active urinary tract or systemic infection • Unable to safely stop anticoagulant or antiplatelet agents perioperatively • Diagnosed or suspected cancer of the prostate

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8. Performance Data

The device's technological characteristics are unchanged, therefore no further non-clinical performance test data is required to support the subject device. The following pre-existing non-clinical data continues to be relied upon to support the safety and effectiveness of the subject device:

- Biocompatibility
- Sterilization
- Software and Firmware Verification
- Electrical Safety and EMC Compatibility
- Usability
- System Design Verification and Validation
- Reliability Testing, AQUABEAM Robotic System

9. Clinical Data Summary

The clinical performance data provided in the submission supports that the contraindication is not required, because the risk of use does not clearly outweigh any possible benefit to patients with diagnosed or suspected prostate cancer.

Previously unsuspected prostate cancer is routinely diagnosed incidentally to surgery for benign prostatic hyperplasia, therefore the existing clinical data generated with the device includes such patients whose prostate cancer was not diagnosed in advance of treatment. A sub-group analysis is performed for participants in the Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue (WATER) study (NCT02505919) without previously diagnosed prostate cancer at the study initiation who went on to be diagnosed with prostate cancer during the study follow-up period.

The clinical performance data also includes a study enumerating circulating tumor cells (CTCs) introduced to the bloodstream secondary to Aquablation in patients with prostate cancer, finding no sustained increase in CTCs following treatment.

10. Conclusion:

The data provided in this submission, together with the prior non-clinical performance testing performed on the predicate device, supports that the AQUABEAM Robotic System with modified labeling is as safe, as effective, and performs as well as the legally marketed predicate device.

The materials provided in this 510(k) premarket notification demonstrate compliance to the special controls prescribed in 21 CFR 876.4350.