June 23, 2026

Procept BioRobotoics
Ankur Kaushal
VP, Global Regulatory Affairs
150 Baytech Drive
San Jose, California 95134

Re: K253211
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: September 26, 2025
Received: September 29, 2025

Dear Ankur Kaushal:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 R. Kreitz -S

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253211

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PROCEPT BioRobotics®

510(k) SUMMARY

Date Prepared: June 23, 2026

Owner/Sponsor	PROCEPT BioRobotics Corporation 150 Baytech Dr., San Jose, 95134 USA
Submitter	Contact Name: Ankur Kaushal Title: VP, Global Regulatory Affairs Address: 150 Baytech Dr., San Jose, CA 95134, USA Telephone: (650) 232-7200 ext. 10378 Email: a.kaushal@procept-biorobotics.com
Trade Name	AquaBeam Robotic System
Classification	Class II
Classification Name	PZP - Fluid jet system for prostate tissue removal
Common Name	Fluid jet system for prostate tissue removal
Common Name and Product Code	PZP A fluid jet system for prostate tissue removal is a prescription device intended for the resection and removal of prostatic tissue for the treatment of benign prostatic hyperplasia (BPH). The device cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra. The device is able to image the treatment area, or pairs with an imaging modality, to monitor treatment progress.
Regulation Number	PZP - 21 CFR 876. 4350

Predicate Device
Trade Name - AQUABEAM ROBOTIC System
510(k) Number – K241952 cleared on September 30, 2024.
Product Code – PZP
Regulation Number: 876. 4350
Device Classification - Class II

Device Description
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

Intended Use/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.

Technological Comparison as compared to the Predicate Device
The subject device remains technologically equivalent to the predicate device.

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 nonclinical 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

Conclusion:
The overall performance, together with the non-clinical performance testing performed on the device, supports that the AquaBeam Robotic System is as safe & effective, and performs as well as the legally marketed predicate device.

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