October 6, 2021

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

Re: K212835
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 3, 2021
Received: September 7, 2021

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, 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)*
K212835

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

Date Prepared

September 30, 2021

Owner/Sponsor

Owner/Sponsor	PROCEPT BioRobotics Corporation 900 Island Drive, Suite 101 Redwood City, 94065 USA
Contact Name: Title: Address: Telephone: Cell: Fax: Email:	Sara Muddell Director of Global Regulatory Affairs 900 Island Drive, Suite 101, Redwood City, CA, 94065, USA (650) 232-7217 (669) 220-8583 (650) 232-5782 s.muddell@procept-biorobotics.com

Device Trade Name
AQUABEAM® Robotic System

Common Name
- AQUABEAM
- AQUABEAM Robotic System
- Fluid jet system for prostate tissue removal

Classification and Classification Name
Class II

Product Code: PZP

21 CFR 876. 4350, Fluid jet system for prostate tissue removal

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.

Predicate Device
AQUABEAM Robotic System
510(k) Number: K202961 on November 04, 2020.
Product Code: PZP
Regulation Number: 876. 4350
Class II

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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

The AQUABEAM Console, Motorpack, Conformal Planning Unit, Foot Pedal, Roll Stand, Handpiece Articulating Arm and TRUS Articulating Arm are provided non-sterile and no sterilization is required prior to each use. The Console, Conformal Planning Unit, Foot Pedal, Roll Stand, Articulating Arms, and Motorpack are cleaned after each use. The Console, Conformal Planning Unit, Foot Pedal, Roll Stand, Articulating Arms, and Motorpack are not designed to come in contact with the patient during the Aquablation procedure.

The Conformal Planning Unit is a reusable component of the AQUABEAM Robotic System, and it serves as the primary user interface of the System. The CPU is connected to the Console via a USB cable.

The AQUABEAM Console is a reusable component of the AquaBeam Robotic System that controls the functionality of the high-velocity waterjet delivered by the Handpiece.

The AQUABEAM Motorpack is a reusable component of the AQUABEAM Robotic System designed to dock, via a mechanical linkage, and connect with the disposable Handpiece. The Motorpack provides mechanical power to the Handpiece by means of DC motors, which enable both rotational and longitudinal movement of the Handpiece probe providing controlled and precise resection of the prostatic tissue in accordance with the CPU treatment plan.

The AQUABEAM Foot Pedal is a reusable, purchased component of the AQUABEAM Robotic System that contains three foot-activated momentary switches. It is connected to the Console with a flexible cable. The Aquablate Pedal is the large center switch which must be depressed to enable Aquablation.

The AQUABEAM Roll Stand provides the main power source, via the isolation transformer, to the Console and serves as the chassis for the AQUABEAM Robotic System.

The AQUABEAM Handpiece Articulating Arm fixes the Handpiece/Motorpack assembly in position relative to the patient. The AQUABEAM TRUS Articulating Arm fixes the TRUS probe and stepper in position relative to the patient. The AQUABEAM Handpiece is a terminally sterilized, single-use disposable component of the AQUABEAM Robotic System.

The AquaBeam Scope, a re-usable component of the AquaBeam Robotic System, needs to be reprocessed prior to each use per the AquaBeam Scope Reprocessing Instructions. The Scope is inserted into the central lumen of the Handpiece enabling direct visualization within the prostatic urethra during treatment.

Intended Use/Indications for Use
The intended use of the subject device is identical to the intended use of the predicate device.

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.

Intended Patient Population
The intended patient population of the subject device is identical to the intended use of the predicate device.

The intended patient population is males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).

Intended Users

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

The intended users are urologists and support staff who are trained and familiar with Transrectal Ultrasound (TRUS) and performing endoscopic surgical benign prostatic hyperplasia procedures and in recognizing and managing their complications.

Technological Characteristics as Compared to the Predicate Device
The technological characteristics of the AQUABEAM Robotic System such as design, material and chemical composition of patient contacting components and energy source remain equivalent to the predicate device, AQUABEAM System. The table below summarizes the comparison between the subject device and the predicate device -

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE	CHANGE
Device Class	Class II	Class II	Same
Product Code	PZP	PZP	Same
Product Regulation Number	21 CFR 876.4350	21 CFR 876.4350	Same

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Intended Use/Indications for Use	The AQUABEAM 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 AQUABEAM 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.	Same
Intended Patient Population	The intended patient population is males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).	The intended patient population is males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).	Same
Intended User	Urologists and support staff who are trained and familiar with performing endoscopic surgical benign prostatic hyperplasia procedures and in recognizing and managing their complications. Users must possess a thorough understanding of the technical principles, clinical application, and risks associated with the AQUABEAM Robotic System and complete the PROCEPT BioRobotics Corporation training program prior to use	Urologists and support staff who are trained and familiar with performing endoscopic surgical benign prostatic hyperplasia procedures and in recognizing and managing their complications. Users must possess a thorough understanding of the technical principles, clinical application, and risks associated with the AQUABEAM Robotic System and complete the PROCEPT BioRobotics Corporation training program prior to use	Same
Patient Contact	The AQUABEAM Robotic System shall be used endoscopically accessing the prostate via the urethra (external communicating device, tissue/bone/dentin, with limited exposure (<24 hours).	The AQUABEAM Robotic System shall be used endoscopically accessing the prostate via the urethra (external communicating device, tissue/bone/dentin, with limited exposure (<24 hours).	Same
Sterilization method	Ethylene Oxide Sterilization (ETO) SAL 10^{-6}	Ethylene Oxide Sterilization (ETO) SAL 10^{-6}	Same
Operating Environment	Temperature: 0° to 35° C Humidity: 0% to 90%, non-condensing Atmospheric Pressure: 70 kPA to 107 kPA	Temperature: 0° to 35° C Humidity: 0% to 90%, non-condensing Atmospheric Pressure: 70 kPA to 107 kPA	Same
Transportation and Storage Environment	Temperature: 0° to 35° C Humidity: 0% to 90%, non-condensing Atmospheric Pressure: 70 kPA to 107 kPA	Temperature: 0° to 35° C Humidity: 0% to 90%, non-condensing Atmospheric Pressure: 70 kPA to 107 kPA	Same

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Use Life of the system	185 cycles	185 cycles	Same
Use Life of the Articulating Arms	200 cycles	200 cycles	Same
Reprocessing Sterilization methods for AQUABEAM Scope	• STERIS System 1E Standard Cycle • STERRAD 100NX Express Cycle • STERRAD NX Standard or Advanced cycle • STERRAD 100S • STERIS V-Pro® 1 Plus – Non Lumen cycle • STERIS V-Pro® maX – Non Lumen cycle • STERIS V-Pro® mAX 2 – Non Lumen cycle • Matachana 130HPO® and 50HPO® - Standard cycle • Getinge GSS67F Low Temperature Steam and Formaldehyde - 55°C Cycle • Ethylene Oxide (EtO)	• STERIS System 1E Standard Cycle • STERRAD 100NX Standard Cycle • STERRAD NX Standard or Advanced cycle • STERRAD 100S • STERIS V-Pro® 1 Plus – Non Lumen cycle • STERIS V-Pro® maX – Non Lumen cycle • STERIS V-Pro® mAX 2 – Non Lumen cycle • Matachana 130HPO® and 50HPO® - Standard cycle • Getinge GSS67F Low Temperature Steam and Formaldehyde - 55°C Cycle Ethylene Oxide (EtO)	Updated the sterilization methods for AQUABEAM Scope to replace STERRAD 100NX Standard cycle with STERRAD 100NX Express cycle.
Use Life of the AQUABEAM Scope (reusable component that requires reprocessing prior to each use)	At least 10 cycles	58 cycles	Updated the use life cycles after adding the STERRAD 100NX Express cycles.
Shelf Life (Handpiece is the single use component provided sterile)	24 months (2 Years)	24 months (2 Years)	Same
Mechanism of Action			
COMPARISON ELEMENT	**SUBJECT DEVICE**	**PREDICATE DEVICE**	**COMMENTS**
Maximum angle rotation	225 degrees	225 degrees	Same
Maximum depth of penetration	24.3 mm	24.3 mm	Same

Subject Device Design Changes

The AQUABEAM Robotic System, subject of this 510(k) includes the following changes:

1. IFU Change – Replacing the scope sterilization cycle STERRAD 100NX Standard with STERRAD 100NX Express cycle.

2. Update to the use life of AQUABEAM Scope - The scope life specification of the AQUABEAM Scopes is updated to at least 10 use cycles.

Summary of Non-Clinical Performance Testing
A list of the verification, validation and other testing that have been performed on the AQUABEAM Scope with the sterilization change is included below.

Non-clinical Testing	Conforming Standard and Guidance
Sterilization Validation testing for AQUABEAM Scope	1. EN ISO 14937: 2009 Sterilization of health care products – general requirements for characterization of sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices 2. ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for invitro cytotoxicity. 3. ISO 10993-12 Biological evaluation of medical devices – Part 5: Sample Preparation and reference materials 4. ISO 17664:2017 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.
AQUABEAM scope Reliability testing	None

The following testing performed on the predicate device is still applicable to the subject device of this Special 510(k):
1. Biocompatibility
2. Clinical Trial data
3. Design Verification and Design Validation testing

Conclusion:
The overall performance data in this submission supports that the AQUABEAM Robotic System is safe, effective, and substantially equivalent to the predicate device when utilized for its intended use.