March 11, 2021

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

Re: K202961
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: February 1, 2021
Received: February 2, 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 801and Part 809); 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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202961

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.

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PROCEPT BioRobotics

Traditional 510(k) application

510(k) SUMMARY

Date of submission:
November 04, 2020

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

Trade/Device Name
AQUABEAM® Robotic System

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

Device Classification Number and Classification Name

21 CFR 876.4350, Fluid jet system for prostate tissue removal

Regulatory Class: II

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.

Predicate Device
Trade Name: AQUABEAM System
510(k) Number: DEN170024 on 21 December 2017.
Product Code: PZP
Regulation Number: 876. 4350
Class II

PROCEPT BioRobotics

Traditional 510(k) application

Submission Number: DEN170024

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.

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.

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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.

	Subject Device AQUABEAM Robotic System	**Predicate Device AQUABEAM System**	**Change**
Device Class	**Class II**	**Class II**	**Same**
Product Code	**PZP**	**PZP**	**Same**
Product Regulation Number	**876.4350**	**876.4350**	**Same**
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.	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.	**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 Users	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	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	**Same**

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	Subject Device AQUABEAM Robotic System	Predicate Device AQUABEAM System	Change
	and in recognizing and managing their complications.	and in recognizing and managing their complications.	
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**
Energy Source	100/115/220/230/240 VAC 1000 W 50/60 Hz	115-230 VAC 600 W 50/60 Hz	Equivalent
Sterilization method	Ethylene Oxide Sterilization (EO) SAL 10^{-6}	Ethylene Oxide Sterilization (EO) 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 106 kPA	Same
Transportation and Storage Environment	Temperature: -18° to 60° C Humidity: 15% to 90%, non-condensing Atmospheric Pressure: 60 kPA to 106 kPA	Temperature: -18° to 60° C Humidity: 15% to 90%, non-condensing Atmospheric Pressure: 70 kPA to 106 kPA	Same
Use Life of the system	185 cycles	3 Years	Changed to represent use life in cycles instead of time duration.
Use Life of the Articulating Arms	200 cycles	4 months (19 cycles)	No change to TRUS articulating arms, the changed use life is due to results from continued testing.
Use Life of the AQUABEAM Scope (reusable component that requires reprocessing prior to each use)	58 cycles	8 months (58 cycles)	Removed the number of months in the subject device, no change to the testing or the AQUABEAM Scope

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	Subject Device AQUABEAM Robotic System	Predicate Device AQUABEAM System	Change
			that resulted in the change
Shelf Life (Handpiece is the single use component provided sterile)	24 months (2 Years)	24 months (2 Years)	Same
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 traditional 510(k) includes the changes listed below. These changes do not impact the mode of operation and/or the mechanism of action of the subject device. The mode of operation and/or mechanism of action of the subject device is the same as that of the predicate device.

Change	Subject device	Predicate device	Reason for change
Network Connectivity	CPU board includes a WIFi chipset allowing network connectivity	Network connectivity is not available.	Allows upload of the encrypted treatment logs to PROCEPT Cloud for future device improvements.
Hardware architecture changes: MCU firmware Updates to console FPGA and Motorpack FPGA	A new firmware was added to the Console, Microcontroller Unit (MCU) Firmware. The Console FPGA and the Motorpack FPGA. Updates to Console FPGA and Motorpack FPGA to accommodate the new MCU firmware.	MCU firmware is not included in the predicate device Console.	Enhance communication with the CPU and the Motorpack FPGA
Hardware changes	Motorpack - New R motor with 24 V capability Console – added SPI cable	Motorpack – R motor without the 24V capability Console: No SPI cable (no MCU) HPP cable exists Tubing exist	Motorpack – new R motor added for improved reliability Console: – SPI cable is needed for communication with the MCU firmware – Enhanced signal integrity of HPP

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	– HPP cable – Flexible expandable tubing		cable – Ease of assembly
Software changes	An optional icon was added on the AQUABEAM Conformal Planning Unit (CPU) Software, Graphical User Interface (GUI) that allows the adjusting of the gain, depth and frequency of the third party TRUS.	Third party TRUS is used for adjusting the gain, depth and frequency.	Thew optional feature is added for ease of use.
Labeling change	Removed contraindication "known allergy to device materials"	Includes contraindication "Known allergy to device materials"	This change is not relevant to the subject or the predicate device and has no impact on the safety and effectiveness of the device.

Performance Data

A list of the non-clinical testing performed on the subject device, AQUABEAM Robotic System to demonstrate substantial equivalence includes verification, validation and other testing is listed below. The non-clinical testing conducted are the same as those completed for the predicate device.

Non-Clinical Testing	Conforming standard	Conclusion
Software and Firmware verification	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes NIST FIPS 140-2, Security Requirements for Cryptographic Modules NIST FIPS 140-2 Suite B Cryptographic Module Non-Proprietary Security Policy	Verification testing was performed on the - CPU software, - Operating system - MCU firmware - Updates to Console FPGA - Updates to Motorpack FPGA The software and firmware performed as intended and all acceptance criteria were met demonstrating substantial equivalence.
Hardware Verification	None	Verification testing was conducted on the: - Console - Motorpack - System The Console, Motorpack and System performed as intended and

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		all acceptance criteria were met demonstrating substantial equivalence.
Electrical Safety and Electromagnetic Compatibility	EMC - 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 Electrical Safety: ANSI AAMI ES 60601-1:2005/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for safety – Collateral Standard: Usability ANSI AAMI IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices IEC 80601-2-77 Edition 1.0 2019-07 Medical electrical equipment - Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of robotically assisted surgical equipment. IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	All testing passed EMC per IEC 60601-1-2 4th edition requirements. All testing passed electrical safety per the standards listed.
System Design Verification	None	Verification testing was performed on the AQUABEAM Robotic system to test the functional and simulated use and all acceptance criteria were met demonstrating substantial equivalence to the predicate device.
System Design Validation	None	A design validation of the AQUABEAM Robotic System was conducted by performing a cadaver study and all acceptance criteria were met demonstrating substantial equivalence to the

		predicate device.
Packaging Validation	ASTM D4169-16 2016-04-01 Standard Practice for Performance Testing of Shipping Containers and Systems ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing ASTMD5276 – Test Method for Drop Test of Loaded Containers by Free Fall ASTM D999 – Test Method for Vibration testing of Shipping Containers ASTM D4728 – Test Method for Random Vibration Testing of Shipping Containers ASTM D6653 – Low pressure (altitude) ASTM D642 – Vehicle Stacking ASTM D6344 – Concentrated Impact	Packaging and transportation validation was performed on the following components with design change: - Console - Motorpack There are no changes to packaging that are subject of this traditional 510(k). The components with design change passed all testing conducted.
Reliability Testing	None	The reliability of the components with design changes were evaluated and the results are equivalent to the predicate device. The use life is documented in the table above and in the product labeling.

The following testing performed on the predicate device are still applicable to the subject device of this traditional 510(k):

1. Biocompatibility – There are no changes to the AQUABEAM handpiece and AQUABEAM Scope subject of this traditional 510(k) that require a reassessment of biocompatibility.
2. Sterilization: There are no changes to the AQUABEAM Handpiece subject of this traditional 510(k) that require a new sterilization validation.
3. Clinical Trial data: Existing clinical trial data is sufficient to establish the safety and effectiveness of the subject device, AQUABEAM Robotic System with the changes in design subject of this traditional 510(k) do not change the mode of operation/mechanism of action of the device.

Conclusion:

The changes subject of this traditional 510(k) do not change the indications for use, intended user, intended use, patient population, treatment access site, device classification, classification regulation and mode of operation (mechanism of action) which remain identical to the predicate device. The overall performance data evaluated through non-clinical testing 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.