December 21, 2017

PROCEPT BioRobotics Corporation
Michael Nketiah
Director of Quality Assurance/Regulatory Affairs
900 Island Drive Suite 101
Redwood Shores, California 94065

Re: DEN170024
Trade/Device Name: AQUABEAM System
Regulation Number: 21 CFR 876.4350
Regulation Name: Fluid jet system for prostate tissue removal
Regulatory Class: Class II
Product Code: PZP
Dated: April 14, 2017
Received: April 17, 2017

Dear Michael Nketiah:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the AQUABEAM System, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the AQUABEAM System, and substantially equivalent devices of this generic type, into Class II under the generic name fluid jet system for prostate tissue removal.

FDA identifies this generic type of device as:

> **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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of

the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On April 17, 2017, FDA received your De Novo requesting classification of the AQUABEAM System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AQUABEAM System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the AQUABEAM System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Injury from device operation causing one or more of the following: • Bleeding • Bruising • Penile or pelvic pain • Dysuria • Incontinence • Bladder or prostate capsule perforation • Sexual dysfunction, including ejaculatory and erectile dysfunction • TransUrethral Resection (TUR) syndrome • Urethral damage causing false passage or stricture • Rectal incontinence / perforation • Embolism	Clinical performance testing Animal testing Labeling Training
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Reprocessing validation Shelf life testing Labeling
Failure to remove target tissue or removal of non-target tissue	Clinical performance testing Animal testing Software verification, validation, and hazard analysis Non-clinical performance testing Labeling

	Training
Electrical shock or electromagnetic interference	Electrical safety testing Electromagnetic compatibility testing Labeling

In combination with the general controls of the FD&C Act, the fluid jet system for prostate tissue removal is subject to the following special controls:

1. Clinical performance testing must evaluate the following:
    a. All adverse events associated with the device; and
    b. Improvement in Lower Urinary Tract Symptoms (LUTS).

2. Physician training must be provided that includes:
    a. Information on key aspects and use of the device; and
    b. Information on how to override or stop resection.

3. Animal testing must demonstrate that the device resects targeted tissue in a controlled manner without injury to adjacent non-target tissues.

4. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    a. Measurement of targeting accuracy and reproducibility of high velocity fluid jet
    b. High pressure fluid jet verification testing at target and non-target tissues

5. Software verification, validation, and hazard analysis must be performed.

6. The patient-contacting elements of the device must be demonstrated to be biocompatible.

7. Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of the device.

8. Performance data must demonstrate the sterility of the patient-contacting components of the device.

9. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

10. Performance data must validate the instructions for reprocessing and reliability of reusable components.

11. Labeling must include the following:
    a. A section that summarizes the clinical testing results, including the adverse event profile and improvement in Lower Urinary Tract Symptoms (LUTS);
    b. A shelf life for single use components;
    c. A use life for reusable components; and
    d. Reprocessing instructions for reusable components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the fluid jet system for prostate tissue removal they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning this classification order, please contact Jessica Cades at 240-402-3900.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health