July 9, 2026

Procept Biorobotics
Ankur Kaushal
Vice President, Global Regulatory Affairs
150 Baytech Dr.
San Jose, California 95134

Re: K260723
Trade/Device Name: HYDROS Robotic System (HY1000);
HYDROS Handpiece (HH1000);
HYDROS TRUS Probe (HU1000)
Regulation Number: 21 CFR 876.4350
Regulation Name: Fluid jet system for prostate tissue removal
Regulatory Class: II
Product Code: PZP, ITX
Dated: June 9, 2026
Received: June 10, 2026

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 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260723

Please provide the device trade name(s).

HYDROS Robotic System (HY1000);
HYDROS Handpiece (HH1000);
HYDROS TRUS Probe (HU1000)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

PROCEPT BioRobotics®

510(k) SUMMARY

Date Prepared: Feb 15, 2026

Owner/Sponsor	PROCEPT BioRobotics Corporation 150 Baytech Drive, San Jose, 95134 USA
Submitter	Contact Name: Ankur Kaushal Title: Vice President, Global Regulatory Affairs Address: 150 Baytech Drive, San Jose, CA 95134, USA Telephone: (650) 232-7200 ext. 10378 Email: a.kaushal@procept-biorobotics.com
Trade Name	1. HYDROS™ Robotic System 2. HYDROS™ TRUS Probe 3. HYDROS™ Handpiece
Classification	Class II
Classification Name	Fluid jet system for prostate tissue removal
Product Code	PZP
Regulation Number	21 CFR 876. 4350

Predicate Device

1. **Primary Predicate**[1]
   Trade Name - HYDROS™ Robotic System
   510(k) Number - K240200 cleared on August 20, 2024.
   Product Code – PZP
   Regulation Number: 876. 4350
   Device Classification - Class II

Device Description

The HYDROS™ Robotic System has three components – the HYDROS Robotic System, HYDROS TRUS Probe, and HYDROS Handpiece.

1. **HYDROS Robotic System**
   The HYDROS Robotic System, consists of the following nine components:
   - HYDROS Tower
   - Touchscreen Interfaces - Monitor that supports the Tower Monitor (Tmon) and Surgeon Monitor (Smon) mounted on a monitor mast
   - HYDROS Software (Clinical Application)
   - HYDROS Operating System (MS Windows)

[1] The predicate device does not have any open design related recalls.

- Embedded Software (Firmware)
- Motorpack
- Handpiece Arm
- TRUS Probe Arm
- Foot Pedal

The HYDROS Robotic System is provided non-sterile, and no sterilization is required prior to each use. The HYDROS Robotic System does not come in contact with the patients during the procedure.

2. **HYDROS TRUS Probe**
   The HYDROS TRUS Probe is a biplane transrectal ultrasound probe that is used in the conjunction with the HYDROS Robotic System and HYDROS Handpiece to provide ultrasound imaging to deliver the AQUABLATION procedure. The HYDROS TRUS Probe is re-usable and provided non-sterile. It is reprocessed prior to each use as per the instructions provided in the IFU.

3. **HYDROS Handpiece**
   The HYDROS Handpiece is the single-use sterile surgical device introduced to the surgical site within the prostate through the urethra to visualize, resect and remove prostatic tissue. The HYDROS Handpiece is integrated with a digital CMOS Scope and is terminally sterilized by Ethylene Oxide (EtO).

Intended Use/Indications for Use
The HYDROS Robotic System is indicated 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 is males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).

Intended Users
The intended user shall be a urologist, supported by OR staff, trained and familiar with performing endoscopic surgical procedures for BPH, such as TURP, and in recognizing and managing their complications. The intended user shall also be trained and familiar with TRUS imaging.

Technological Comparison as compared to the Predicate Device
The technological differences between the subject and predicate device are limited to the following:

1. Modifications to various waterjet parameters; and
2. Expanding automated registration features associated with FirstAssist AI.

Non-Clinical Performance Data

Verification and validation testing consisted of the following testing:

- Simulated use testing
- Cadaver Testing
- EMC testing in accordance with IEC 60601-1-2:2020
- Software testing
- Cybersecurity testing

The subject device met all predetermined acceptance criteria. The testing confirmed that the subject device is safe and effective and no additional unexpected risks were identified.

Conclusion

The subject device has the same indications for use and principles of operation as the predicate device. Based on the performance data, provided in this submission, the subject device is substantially equivalent to the predicate device.