October 10, 2025

Procept BioRobotics
Bijesh Chandran
Senior Vice President, Regulatory Affairs and Quality Assurance
150 Baytech Drive
San Jose, California 95134

Re: K251082
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: Class II
Product Code: PZP, ITX
Dated: September 14, 2025
Received: September 15, 2025

Dear Bijesh Chandran:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 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)*
K251082

Device Name
HYDROS Robotic System (HY1000)
HYDROS Handpiece (HH1000)
HYDROS TRUS Probe (HU1000)

Indications for Use *(Describe)*
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.

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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510(k) SUMMARY

Date Prepared: Sep 12, 2025

Owner/Sponsor	PROCEPT BioRobotics Corporation 150 Baytech Drive, San Jose, 95134 USA
Submitter	Contact Name: Bijesh Chandran Title: SVP, Regulatory Affairs and Quality Assurance Address: 150 Baytech Drive, San Jose, CA 95134, USA Telephone: (650) 232-7203 Email: b.chandran@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)
   - HYDROS Software
   - HYDROS Operating System
   - Embedded Software
   - 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 Tower, Foot Pedal, Roll Stand, Articulating Arms, and Motorpack are reprocessed per instructions provided with the device after 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 EtO.

[1] The predicate device has not been subject to any design related recall.

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

HYDROS ROBOTIC SYSTEM

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS ROBOTIC SYSTEM		
Device Trade Name	HYDROS® Robotic System	HYDROS® Robotic System
Manufacturer	PROCEPT BioRobotics Corporation	PROCEPT BioRobotics Corporation
REF/Model Number	HY1000	HY1000
Pre-Market Notification Type	Traditional 510(k)	Traditional 510(k)
510(k) number	K251082	K240200
Regulation Number	21 CFR 876.4350	21 CFR 876.4350
Regulation Name	Fluid jet system for prostate tissue removal	Fluid jet system for prostate tissue removal
Product Classification	Class II	Class II
Product Code	PZP	PZP
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.	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 User	The intended user shall be a urologist, supported by	The intended user shall be a urologist, supported by OR

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS ROBOTIC SYSTEM		
	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.	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.
Patient Population	Males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).	Males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).
Intended Body/Tissue Interaction	The HYDROS Robotic System is not patient contacting.	The HYDROS Robotic System is not patient contacting.
Operating Environment	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA
Storage Environment	Temperature: 10° to 30° Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA	Temperature: 10° to 30° Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA
Transportation 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: 60 kPA to 106 kPA
Cleaning and Disinfection Method	Clean using quaternary ammonium –based cleaner and disinfect using intermediate level disinfectant.	Clean using quaternary ammonium –based cleaner and disinfect using intermediate level disinfectant.
Use Life	1 year	1 year

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS ROBOTIC SYSTEM		
Surgeon Interface	- Two monitors for display – one surgeon monitor (Smon) for use in the sterile environment and the tower monitor (Tmon) which can be used by support staff. - Portrait view - Interaction is through touchscreen. - Physician authorization is enabled on the surgeon monitor or by pressing the + button on the motorpack.	- Two monitors for display – one surgeon monitor (Smon) for use in the sterile environment and the tower monitor (Tmon) which can be used by support staff. - Portrait view - Interaction is through touchscreen. - Physician authorization is enabled only on the surgeon monitor.
Ultrasound	Integrated ultrasound and a compatible TRUS probe is provided with the HYDROS Robotic System.	Integrated ultrasound and a compatible TRUS probe is provided with the HYDROS Robotic System.
Cystoscope Imaging	The CMOS scope connects to the HYDROS Robotic System and specifically the camera control unit (CCU) located within the tower infrastructure of the device for cystoscope image processing.	The CMOS scope connects to the HYDROS Robotic System and specifically the camera control unit (CCU) located within the tower infrastructure of the device for cystoscope image processing.
Maximum angle rotation	225 degrees	225 degrees
Maximum depth of penetration	24.3 mm	24.3 mm
Network Connection Capability	The HYDROS Robotic System component (PC) includes a Wi-Fi card that creates network connection capability.	The HYDROS Robotic System component (PC) includes a Wi-Fi card that creates network connection capability.
Cloud Connection + Wi-Fi connection	The software allows enabling and disabling the cloud connection on the Wi-Fi connected systems.	The software allows enabling and disabling the cloud connection on the Wi-Fi connected systems.

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS ROBOTIC SYSTEM		
	Users have the option to choose a disconnected system.	Users have the option to choose a disconnected system.
FirstAssist AI™ (previously Assisted Planning) Feature	Optional FirstAssist AI feature available during the PLAN step. FirstAssist AI , Transverse: When the FirstAssist AI toggle button is enabled in the transverse view at the angle and depth step, the software provides the handpiece nozzle position and the prostate capsule boundary. FirstAssist AI , Sagittal: When the FirstAssist AI toggle button is enabled at the profile landmark step the software will place the 4 landmarks – treatment start (TS), blader neck (BN), mid-prostate (MP) and treatment end (TE). The surgeon has the option to adjust the landmarks as needed. The subject device has an updated AI model for the same functionality of landmark identification.	Optional FirstAssist AI feature available during the PLAN step. FirstAssist AI , Transverse: When the FirstAssist AI toggle button is enabled in the transverse view at the angle and depth step, the software provides the handpiece nozzle position and the prostate capsule boundary. FirstAssist AI , Sagittal: When the FirstAssist AI toggle button is enabled at the profile landmark step the software will place the 4 landmarks – treatment start (TS), blader neck (BN), mid-prostate (MP) and treatment end (TE). The surgeon has the option to adjust the landmarks as needed.
Workflow Optimization	GUI Steps: • Setup – includes TRUS, Handpiece and Align – Plan -includes Manual and optional FirstAssist AI Transverse	GUI Steps: • Setup – includes TRUS, Handpiece and Align • Plan -includes Manual and optional FirstAssist AI Transverse Angle and Depth planning options, registration,

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS ROBOTIC SYSTEM		
	Angle and Depth planning options, registration, Manual and Optional FirstAssist AI profile options for Sagittal Plane and Contour. • Treat – includes treatment with the options for starting an additional pass or completing the procedure.	Manual and Optional FirstAssist AI profile options for Sagittal Plane and Contour. Treat – includes treatment with the options for starting an additional pass or completing the procedure.
Manual Aspiration Flow Rate	During Resection: Nominal Waterjet Flow + 10ml/min Manual: 360±75ml/min = [285, 435]	During Resection: Nominal Waterjet Flow + 10ml/min Manual: 360±75ml/min = [285, 435]
Verumontanum protection orientation	• Transverse Plane - The user cannot modify the default orientation of the verumontanum protection zone. • Sagittal Plane - The user has the ability to modify the length of the verumontanum protection zone.	• Transverse Plane - The user cannot modify the default orientation of the verumontanum protection zone. • Sagittal Plane - The user has the ability to modify the length of the verumontanum protection zone.

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HYDROS TRUS PROBE

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS TRUS Probe		
Device Trade Name	HYDROS TRUS Probe	HYDROS TRUS Probe
Manufacturer	PROCEPT BioRobotics Corporation	PROCEPT BioRobotics Corporation
REF/Model Number	HU1000	HU1000
Pre-Market Notification Information	Traditional 510(k)	Traditional 510(k)
510(k) number	K251082	K240200
Regulation Number	21 CFR 876.4350	21 CFR 876.4350
Regulation Name	Fluid jet system for prostate tissue removal	Fluid jet system for prostate tissue removal
Product Classification	Class II	Class II
Product Code	PZP, ITX	PZP. ITX
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.	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 User	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.	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.
Patient Population	Males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).	Males suffering from LUTS resulting from benign prostatic hyperplasia (BPH).
Intended Body/Tissue interaction	The HYDROS TRUS probe may come in contact with the rectal tissue. Tissue/Bone/Dentin per ISO 10993-1:2018, Table A.1	The HYDROS TRUS probe may come in contact with the rectal tissue. Tissue/Bone/Dentin per ISO 10993-1:2018, Table A.1

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS TRUS Probe		
Duration of Contact	The HYDROS TRUS probe is considered an Externally communicating medical device. The HYDROS TRUS probe is used as part of the Aquablation procedure which lasts about 30 minutes, so the TRUS probe has Limited Exposure (≤24hr).	The HYDROS TRUS probe is considered an Externally communicating medical device. The HYDROS TRUS probe is used as part of the Aquablation procedure which lasts about 30 minutes, so the TRUS probe has Limited Exposure (≤24hr).
Mode of Action	B mode	B mode
Surface Area (patient contacting portion of the probe only)	~276 Sq.cm	~276 Sq.cm
Plane Switching	The handle interface of the HYDROS TRUS probe provides a button to switch ultrasound visualization planes between transverse and sagittal planes	The handle interface of the HYDROS TRUS probe provides a button to switch ultrasound visualization planes between transverse and sagittal planes
Connection	Probe is plugged into the HYDROS Robotic System with one connector	Probe is plugged into the HYDROS Robotic System with one connector
Length of the connector cable	~220 cm	~220 cm
Materials	HYDROS TRUS probe material information: - Hard Shell: ABS Plastic - Transducer portion of the probe: Silicone - Plane Switching Button: Silicone	HYDROS TRUS probe material information: - Hard Shell: ABS Plastic - Transducer portion of the probe: Silicone - Plane Switching Button: Silicone
Reprocessing	Reprocessing is required prior to each use and instructions are provided in the instructions for use (IFU) shipped with device. Addition of two reprocessing methods to the TRUS Probe IFU: 1. Disinfection using CIDEX™ OPA (ASP™).	Reprocessing is required prior to each use and instructions are provided in the instructions for use (IFU) shipped with device.

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS TRUS Probe		
	2. Sterilization using STERIS V-Pro maX Non-Lumen cycle.	
Operating Environment	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70kPA to 101kPA	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70kPA to 101kPA
Storage Environment	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70kPA to 101kPA	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70kPA to 101kPA
Transportation Environment	Temperature: -18° to 60° C Humidity: 15% to 90%, non-condensing Atmospheric Pressure: 60kPA to 106kPA	Temperature: -18° to 60° C Humidity: 15% to 90%, non-condensing Atmospheric Pressure: 60kPA to 106kPA
Use Life	The users are instructed to perform visual and functional inspection post reprocessing and prior to each use however, the device is validated for 71 cycles of reprocessing.	The users are instructed to perform visual and functional inspection post reprocessing and prior to each use however, the device is validated for 25 cycles of reprocessing.

HYDROS HANDPIECE

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS HANDPIECE		
Device Trade Name	HYDROS Handpiece	HYDROS Handpiece
Manufacturer	PROCEPT BioRobotics Corporation	PROCEPT BioRobotics Corporation
REF/Model Number	HH1000	HH1000
Pre-Market Notification Information	Traditional 510(k)	Traditional 510(k)
510(k) number	K251082	K240200
Regulation Number	21 CFR 876.4350	21 CFR 876.4350

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS HANDPIECE		
Regulation Name	Fluid jet system for prostate tissue removal	Fluid jet system for prostate tissue removal
Product Classification	Class II	Class II
Product Code	PZP	PZP
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.	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 User	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.	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.
Patient Population	Males suffering from LUTS resulting from benign prostatic hyperplasia (BPH)	Males suffering from LUTS resulting from benign prostatic hyperplasia (BPH)
Intended Body/Tissue Interaction	The HYDROS Handpiece shall be used endoscopically accessing the prostate via the urethra (external communicating device, tissue/bone/dentin, with limited exposure (<24 hours).	The HYDROS Handpiece shall be used endoscopically accessing the prostate via the urethra (external communicating device, tissue/bone/dentin, with limited exposure (<24 hours).
Biocompatibility	The device was tested for biocompatibility as per the ISO 10993-1 standard and it was reported to be biocompatible.	The device was tested for biocompatibility as per the ISO 10993-1 standard and it was reported to be biocompatible.
Sterilization method	Ethylene Oxide Sterilization (ETO) SAL 10-6	Ethylene Oxide Sterilization (ETO) SAL 10-6
Operating Environment	Temperature: 10° to 30° C	Temperature: 10° to 30° C

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS HANDPIECE		
	Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA	Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA
Storage Environment	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA	Temperature: 10° to 30° C Humidity: 20% to 80%, non-condensing Atmospheric Pressure: 70 kPA to 101 kPA
Transportation 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: 60 kPA to 106 kPA
Shelf Life of the Handpiece	24 months	6 months
Use Life of the scope	Single use	Single use
Scope	The CMOS Scope is a digital scope and comes pre-loaded in the HYDROS Handpiece. This CMOS Scope is a single-use device and provided sterile.	The CMOS Scope is a digital scope and comes pre-loaded in the HYDROS Handpiece. This CMOS Scope is a single-use device and provided sterile.
Maximum angle rotation	225 degrees	225 degrees
Maximum depth of penetration	24.3 mm	24.3 mm
Resolving Power	(MTF) • >80% contrast at 80 lp/ph (8 lp/mm object space) @5mm • >80% contrast at 80 lp/ph (5.3 lp/mm object space) @8mm	(MTF) • >80% contrast at 80 lp/ph (8 lp/mm object space) @5mm • >80% contrast at 80 lp/ph (5.3 lp/mm object space) @8mm
Field of View	Minimum of 60° FoV	Minimum of 60° FoV
Working Length	24.5cm ≥ working length ≤ 27.0cm Maximum = 24 Fr	24.5cm ≥ working length ≤ 27.0cm Maximum = 24 Fr
Packaging	HYDROS Handpiece will be packaged in a thermoformed Tray and Retainer manufactured using PETG.	HYDROS Handpiece will be packaged in a thermoformed Tray and Retainer manufactured using PETG.

COMPARISON ELEMENT	SUBJECT DEVICE	PREDICATE DEVICE
HYDROS HANDPIECE		
	The tray and the retainer are heat sealed using a Tyvek lid.	The tray and the retainer are heat sealed using a Tyvek lid.

Non-Clinical Performance Data

Design validation included simulated use testing and cadaver testing.

Please see table below for testing conducted in accordance with applicable standards and guidance documents on the HYDROS Robotic System and its components.

Summary of non-clinical testing in accordance with applicable standards and guidance documents

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
System Verification	FDA Guidance	Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	Pass
Usability	IEC 62366-1:2015/COR1:2016	Medical devices – Part 1: Application of usability engineering to medical devices	Pass
	ANSI/AAMI HE75:2009 (R2018)	Human Factors Engineering - Design Of Medical Devices	
Electromagnetic Compatibility	IEC60601-1-2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	Pass
	IEC TR 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	
Basic Safety	IEC 60601-1:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
	IEC 60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
	EC 60601-1-6:2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard:Usability	
	IEC 60601-2-18: 2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	
	IEC 80601-2-77: 2019	Medical electrical equipment - Part 2-77: Particular requirements for the Basic Safety and essential performance of Robotically Assisted Surgical Equipment (RASE)	
Wireless	AAMI TIR69:2017/(R2020)	Technical Information Report Risk Management of radio-frequency wireless coexistence for medical devices and systems	Pass
	FDA Guidance	Radio Frequency Wireless Technology in Medical Devices	
Sterilization	EN ISO 11135:2014 + AMD 1: 2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Pass
	ISO 10993-7:2008 + AMD 1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	
	ISO 11138-1: 2017	Sterilization of health care products — Biological indicators — Part 1: General requirements	
	ISO 11138-2: 2017	Sterilization of health care products — Biological	

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
		indicators — Part 2: Biological indicators for ethylene oxide sterilization processes	
	BS EN 556-1: 2001	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices	
	ISO11737-1: 2018+AMD1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	
	ISO 11737-2: 2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process	
	ISO 11139: 2018	Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards	
	ISO 14937:2009	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices	
	AAMI TIR 14: 2016	Contract sterilization using ethylene oxide	
	AAMI TIR 15: 2016	Physical aspects of ethylene oxide sterilization	

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
	AAMI TIR 16: 2017	Microbiological aspects of ethylene oxide sterilization	
	ISO 14937:2009	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	
	AAMI TIR 28: 2016/(R)2020	Product adoption and process equivalence for ethylene oxide sterilization	
	ISO 11135 Second edition 2014-07-15	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]	
	ISO 11737-2 Third edition 2019-12	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	
Biocompatibility	ISO 10993-1:2018	Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process	Pass
	ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	
	ISO 10993-5:2009	Biological evaluation of medical devices - Part5: Tests for in vitro cytotoxicity	
	ISO 10993-9: 2019	Biological evaluation of medical devices — Part 9: Framework for identification	

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
		and quantification of potential degradation products	
	ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	
	ISO 10993-11: 2017	Biological evaluation of medical devices – Part 11: Tests for Systemic Toxicity	
	ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	
	ISO 10993-13:2010	Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices	
	ISO 10993-14:2001	Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics	
	ISO 10993-15:2019	Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys	
	ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process	
	ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for Irritation	
Packaging and Transit	ISTA 3B: 2017	Packaged-Products for Less-Than-Truckload (LTL) Shipment	Pass

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
	ASTM D4332-22	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	
	ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems	
	ASTM F1886/F1886M-16	Standard test method for determining integrity of seals for flexible packaging visual inspection	
	ASTM F2096-11 (2019)	Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test)	
	ISO 11607-1: 2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	
	ISO 11607-2: 2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	
Shelf Life	ASTM F88/F88- 2023	Standard test method for seal strength of flexible barrier materials	Pass
	ASTM F1980-21	Standard guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices	
Reliability	MIL-STD-721C	Military Standards Definitions of Terms for Reliability and Maintainability	Pass
Labeling	ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and	Pass

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
		information to be supplied - Part 1: General requirements	
	ISO 20417:2021	Medical devices — Information to be provided by the manufacturer	
	ISO 7000:2019	Graphical symbols for use on equipment - Registered symbols	
	ISO 7010 Third edition 2019-07	Graphical symbols - Safety colours and safety signs - Registered safety signs	
	ISO 17664-2 First edition 2021-02	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.	
	IEC/TR 60878 Ed. 4.0 2022-11	Graphical symbols for electrical equipment in medical practice	
	ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices	
	FDA Guidance	Device Labeling Guidance #G91-1 (Blue Book Memo)	
	FDA Guidance	Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)	
Reprocessing	ANSI AAMI ST98:2022	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices	Pass
	AAMI TIR 12:2020	Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A	

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
		Guide For Device Manufacturers	
	ASTM F3208-20	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices	
	AAMI TIR 99:2024	Processing of dilators, transesophageal and ultrasound probes in health care facilities	
Corrosion	ASTM F1089-18	Standard Test Method for Corrosion of Surgical Instruments	Pass
Cystoscope Imaging	ISO 8600-5:2020	Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics	Pass
	ISO 8600-3:2019	Endoscopes – Medical endoscopes and endotherapy devices – Part 3: Determination of field of view and direction of view of endoscopes with optics	
	ISO 8600-1: 2015	Endoscopes – medical and endotherapy devices – Part 1: General Requirements	
	ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications	
	ISO CIE 11664-4, First Edition 2019-06	Colorimetry - Part 4: CIE 1976 L*a*b colour space	
	ISO CIE 11664-6, First Edition 2014-02-01	Colorimetry - Part 6: CIEDE2000 colour difference formula	
	IEC 61966-2-1:1999-10	Multimedia systems and equipment - Colour measurement and management - Part 2-1:	

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
		Colour management - Default RGB colour space - sRGB	
Ultrasound Imaging	IEC 62127-1:2022	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields	Pass
	IEC 61391-1:2006+AMD1:2017	CSV Consolidated version Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of point-spread function response	
	FDA Guidance	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	
Cybersecurity	ISO IEC 29147 First edition 2014-02-15	Information technology - Security techniques - Vulnerability disclosure	Pass
	IEC 80001-1 Edition 1.0 2010-10	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities	
	AAMI TIR57:2016	Principles for medical device security - Risk management.	
	ANSI NEMA HN 1-2019	American National Standard Manufacturer Disclosure Statement for Medical Device Security	
	FDA Guidance	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	
	FDA Guidance	Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software	
Software	FDA Guidance	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Pass

Non-Clinical Bench Tests	Guidance/Standard ID	Guidance/Standard Name	Results
	Draft FDA Guidance	Draft Guidance - Content of Premarket Submissions for Device Software Functions	
	FDA Guidance	General Principles of Software Validation	
AI/ML	FDA Guidance	Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions	Pass
	FDA Guidance	Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions	
	FDA Guidance	Good Machine Learning Practice for Medical Device Development: Guiding Principles	

Conclusion:
The overall performance data in this submission supports that the HYDROS Robotic System and its components are substantially equivalent to the predicate device when utilized for its intended use.