April 7, 2022

Green OR, LLC.
% Aaron Rogers
Director of Regulatory and Quality
Pathway LLC
8779 Cottonwood Ave, Suite 105
Santee, California 92071

Re: K211203
Trade/Device Name: Green OR Reprocessed Aquamantys Bipolar Sealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: March 7, 2022
Received: March 8, 2022

Dear Aaron Rogers:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Reprocessed Single-Use Device Models Included in Submission:

OM	Model Number	Device Name/Description
Medtronic	23-113-1	Aquamantys 2.3 Bipolar Sealer
Medtronic	23-112-1	Aquamantys 6.0 Bipolar Sealer
Medtronic	23-313-1	Aquamantys 9.5 XL Bipolar Sealer

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)*
K211203

Device Name
Green OR Reprocessed Aquamantys 2.3 Bipolar Sealer, Green OR Reprocessed Aquamantys 6.0 Bipolar Sealer, Green OR Reprocessed Aquamantys 9.5 XL Bipolar Sealer

Indications for Use *(Describe)*
The Green OR Reprocessed Aquamantys Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with a qualified Pump Generator for delivery of radio-frequency (RF) energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

The Green OR Reprocessed Aquamantys 2.3 Bipolar Sealer is intended for, but not limited to orthopaedic, neurosurgical, spine, thoracic, and open abdominal surgery.

The Green OR Reprocessed Aquamantys 6.0 Bipolar Sealer is intended for, but not limited to orthopaedic, spine, thoracic, and open abdominal surgery.

The Green OR Reprocessed Aquamantys 9.5 XL Bipolar Sealer is intended for, but not limited to open abdominal, orthopaedic, and thoracic surgery.

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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K211203

Reprocessed
Aquamantys
Bipolar Sealers

K211203 Summary

SUBMITTER	Green OR, LLC. John Zehren 4200 Dahlberg Drive #300 Golden Valley, MN 55422
CONTACT	Aaron Rogers Pathway, LLC. 8779 Cottonwood Ave. #105 Santee, CA 92071 619-415-0103 x704 arogers@pathwaynpi.com
DATE PREPARED	April 6, 2022
DEVICE NAME	Green OR Reprocessed Aquamantys Bipolar Sealer
CLASSIFICATION	Electrosurgical cutting and coagulation device and accessories Regulation: 21 CFR 878.4400 Device Class: Class II Product Code: NUJ
PREDICATE DEVICE	

Predicate Manufacturer	Device Name	510(k)
Medtronic	Aquamantys 2.3 Bipolar Sealer	K132974
Medtronic	Aquamantys 9.5 XL Bipolar Sealer	K120537
Medtronic	Aquamantys 6.0 Bipolar Sealer	K111285

REFERENCE DEVICE	No reference devices were used in this submission.
DEVICE DESCRIPTION	The Reprocessed Aquamantys Bipolar Sealer is a sterile, single-use device. The device employs radio-frequency (RF) energy and saline irrigation for hemostatic sealing and coagulation, and blunt dissection (9.5 only). The device is equipped with a dual electrode tip with saline apertures at its distal end. Saline and electrical lines exit the opposite end of the handpiece from the electrodes. The handpiece is equipped

	with an on-off button that simultaneously activates both RF and saline flow. A saline fluid delivery line is provided with the device, and includes a section of pump tubing and a drip chamber or spike. The three-pin electrical connector is designed to be plugged into a qualified Pump Generator. The generator is not included in the scope of the study and will not be reprocessed.
INTENDED USE	The Green OR Reprocessed Aquamantys Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with a qualified Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. The device is not intended for contraceptive tubal coagulation (permanent female sterilization). The Green OR Reprocessed Aquamantys 2.3 Bipolar Sealer is intended for, but not limited to orthopaedic, neurosurgical, spine, thoracic, and open abdominal surgery. The Green OR Reprocessed Aquamantys 6.0 Bipolar Sealer is intended for, but not limited to orthopaedic, spine, thoracic, and open abdominal surgery. The Green OR Reprocessed Aquamantys 9.5 XL Bipolar Sealer is intended for, but not limited to, open abdominal, orthopaedic, and thoracic surgery.
TECHNOLOGICAL CHARACTERISTICS	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate device. The subject devices are a reprocessed version of the predicate. The predicate devices were used to support intended use, technological characteristics, and functional performance specifications.

PERFORMANCE TESTING	The functional characteristics of the subject devices have been evaluated and found to be equivalent to the predicate devices based on the following tests:
	• Sterilization Validation
	• Biocompatibility
	  • Cytotoxicity
	  • Sensitization
	  • Irritation: Intracutaneous Reactivity
	  • Acute systemic toxicity
	  • Material mediated pyrogenicity
	  • Bacterial Endotoxin / LAL
	• EMC and Electrical Safety
	  • IEC 60601-2-2
	• Functional Performance
	  • RF Power Output
	  • Saline Flow Rate
	• Thermal Effects Testing

	• Cleaning
	  • Residual Protein
	  • Residual Total Organic Carbon

CONCLUSION	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, the Green OR Reprocessed Aquamantys Bipolar Sealer is substantially equivalent to the predicate devices.