December 9, 2022

Stryker Instruments
Tu Nguyen
Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K222552
Trade/Device Name: 120V Neptune S Rover (0711-001-000);V2 4-Port Manifold (0750-400-000);V2 Specimen Collection Manifold Kit (0750-200-000);V2 Specimen Collection Tray (0750-210-000)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: November 7, 2022
Received: November 9, 2022

Dear Tu Nguyen:

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,

Jessica Carr -S

for 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

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.

Submission Number *(if known)*

K222552

Device Name

120V Neptune S Rover (0711-001-000);
V2 4-Port Manifold (0750-400-000);
V2 Specimen Collection Manifold Kit (0750-200-000);
V2 Specimen Collection Tray (0750-210-000)

Indications for Use *(Describe)*

The Neptune S Waste Management System is indicated for use in procedures where collecting and disposing of fluid waste and capturing suctioned tissue specimens is desired. It is intended to be used in operating rooms, pathology, surgical centers, procedure rooms, and for endoscopic procedures, such as colonoscopies, esophagogastroduodenoscopies (EGDs), and bronchoscopies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1.0 Applicant Information

1.1 Applicant Name and Address

Stryker Instruments
1941 Stryker Way
Portage, MI 49002, USA

1.2 Contact Information

Contact Name: Tu Nguyen
Telephone Number: (817) 932-4541
Email: tu.nguyen2@stryker.com

2.0 Device Information

2.1 Device Name

Trade Name	Neptune S Waste Management System
Common name	Portable suction device
Model Numbers	0711-001-000 (120V Neptune S Rover) 0750-400-000 (V2 4-Port Manifold) 0750-200-000 (V2 Specimen Collection Manifold Kit) 0750-210-000 (V2 Specimen Collection Tray)
Classification	Class 2
Classification Name	Powered suction pump
Regulation Number	878.4780
Product Code	JCX (Class 2) - Apparatus, Suction, Ward Use, Portable, Ac-Powered

2.2 Legally Marketed Predicate Devices

Predicate Device Trade Name	510(k)	Product Code	Manufacturer
Neptune 3 Waste Management System	K153407	JCX	Stryker Instruments 1941 Stryker Way Portage, MI 49002
Neptune 2 Manifolds	K132671	JCX	Stryker Instruments 1941 Stryker Way Portage, MI 49002

2.3 Device Description

The Neptune S Waste Management System includes subject devices Neptune S Rover and V2 Manifolds, previously 510k cleared Neptune 2 Docker, and supporting accessories.

Neptune S Rover is a mobile device, plugged into a standard 15A hospital-grade AC power outlet and is used to suction and collect waste fluids during surgical or nonsurgical procedures. It can also be used to collect tissue specimens suctioned during these procedures. The Rover

provides fluid waste management, fluid volume measurement and contains features designed to specifically aid with tissue specimen collection, including an array of lighting features and a flat worksurface. It was designed with a smaller footprint to accommodate smaller operating rooms or procedure rooms, particularly endoscopy suites.

The manifolds are non-sterile, single-use disposables, that act as an interface between the Rover canister and standard medical grade suction tubing. They facilitate the collection of surgical tissue and the removal of fluid waste.

2.4 Indication for Use

The Neptune S Waste Management System is indicated for use in procedures where collecting and disposing of fluid waste and capturing suctioned tissue specimens is desired. It is intended to be used in operating rooms, pathology, surgical centers, procedure rooms, and for endoscopic procedures, such as colonoscopies, esophagogastroduodenoscopies (EGDs), and bronchoscopies.

2.5 Indication for Use Comparison

The indication for capturing suctioned tissue specimen on Neptune S Waste Management System is not a new intended use or feature of the product as compared to the predicate device because indication for tissue specimen collection is already in scope of predicate device. It is simply being described more directly within the indications for use section of the Neptune S's product labeling.

The addition of use in endoscopic procedures such as colonoscopy, esophagogastroduodenoscopy (EGD), and bronchoscopy is also not a new intended use of the product as compared to the predicate because these specific indications ordinarily fall within the general use of both the subject device and predicate device.

Substantial equivalence of the addition of these specific indications compared to the predicate IFU was additionally supported by the assessment of clinical evidence as described in Section 2.8 below.

In conclusion, the intended use of the Neptune S Waste Management System is the same as the predicate device.

2.6 Technological Comparison

The technological comparison between the subject devices (Neptune S Rover and V2 Manifolds) and the predicate devices (Neptune 3 Rover and Neptune 2 Manifolds) is included in table below. The Neptune 3 Waste Management System was cleared under 510(k) number K153407. The Neptune 2 Manifolds, which is used in Neptune 3 Waste Management System, was cleared under 510(k) number K132671.

Item	Subject Device: Neptune S Rover and V2 Manifolds	Predicate Device: Neptune 3 Rover and Neptune 2 Manifolds
Main System Components	Neptune S Rover V2 Manifolds: 4-port, specimen collection	Neptune 3 Rover Neptune 2 Manifolds: 1-port, 4-port, 4-port specimen collection
Operating Principle	Fluid waste is suctioned from the surgical site through suction tubes connected to the inlet port(s) of a disposable, nonsterile, single patient use manifold installed in the rover. Suction is created via an integrated vacuum pump. The manifold facilitates the collection of surgical tissue and the removal of fluid waste. Once suctioned, the fluid waste is collected in the internal canister of the rover during a procedure. The rover provides fluid waste management, fluid volume measurement, a lighted canister for viewing of canister contents, a specimen light for viewing captured tissue specimen, and a lighted work surface for specimen transfer. Fluid volume measurements are shown on the main control panel display and the secondary control panel display. After use in a procedure, the rover is relocated and attached to the docker, which is typically installed in a healthcare facility waste disposal area. Once the rover is attached, the docker empties the rover's canister of fluid waste for subsequent disposal. Cleaning of the interior of the	Fluid waste is suctioned from the surgical site through suction tubes connected to the inlet port(s) of a disposable, nonsterile, single patient use manifold installed in the rover. Suction is created via an integrated vacuum pump. The manifold facilitates the collection of surgical tissue and the removal of fluid waste. Once suctioned, the fluid waste is collected in 2 internal canisters of the rover during a procedure. The rover provides fluid waste management, fluid volume measurement, a lighted canister for viewing of canister contents, a motorized IV pole, and a smoke evacuation unit. Fluid volume measurements are shown on the main control panel display and the top swivel display. After use in a procedure, the rover is relocated and attached to the docker, which is typically installed in a healthcare facility waste disposal area. Once the rover is attached, the docker empties the rover's canisters of fluid waste for subsequent disposal. Cleaning of the interior of

	canister takes place immediately after the removal of fluid waste.	the canister takes place immediately after the removal of fluid waste.
Energy Source	120V, 60Hz, 6A	120V, 60Hz, 12A
Intended Use Environment	Operating rooms, pathology, surgical centers, procedure rooms	Operating room, pathology, surgical centers, and doctor's offices
User Interface	7" LCD touchscreen Membrane Control Panel Suction Control Dial	8.4" LCD touchscreen 7" Top Display Suction Control Dials

2.7 Non-Clinical Tests Summary & Conclusion

The function and performance of the subject devices (Neptune S Waste Management System) have been evaluated through non-clinical design verification and validation testing. The results of the evaluation tests demonstrate that the subject devices successfully meet the requirements of their intended use. A summary of the testing and the results are included in the table below.

Test Item	Summary of Testing
Intended Use/ User Needs	The subject devices were validated with intended users in simulated use tests to ensure the user needs and intended use requirements were met. All requirements were met and no new issues of safety or effectiveness were raised.
Safety	Verified the effectiveness of all risk controls determined in the device risk analysis. No new issues of safety or effectiveness were raised.
General Requirements and Performance	Verified all components against their design specifications. All requirements were met and no new issues of safety or effectiveness were raised.
Software	Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002. All requirements were met and no new issues of safety or effectiveness were raised.
Electrical, Mechanical, and Thermal Safety	Verified conformance to IEC 60601-1: 2012, IEC 60601-1-6: 2013, IEC 60601-1-8: 2012, IEC 62366:2014
Electromagnetic Compatibility	Verified conformance to IEC 60601-1-2: 2020, CISPR 11 Group 1, Class A requirements as well as additional testing to verify compatibility with RFID devices operating in the 125 - 134 kHz and 13.56 MHz frequency band.
Shipping	The functionality of the devices after simulated shipping conditions was verified. No new issues of safety or effectiveness were raised.

2.8 Clinical Test Summary &Conclusion

The safety and effectiveness of the subject devices in proposed indications for use have been evaluated using retrospective clinical data collected through Post Market Clinical Follow-up (PMCF) survey of predicate device (Neptune 3 Waste Management System) in colonoscopies, EGDs and bronchoscopies procedures. The predicate device performed as expected with no adverse event observed. The data showed 98.3% success rate of all waste fluid and debris removed and 94.7% without removing excess waste fluid and debris than planned. Analysis and evaluation of PMCF data shows that no safety issues or adverse events related to the use of the devices in the clinical procedures as stated in the indications for use.

2.9 Conclusion

The subject device, Neptune S Waste Management System, including the Neptune S Rover and the V2 Manifolds, perform as intended and are at least as safe and effective their respective predicate devices with regard to intended use, design, principles of operation, technology, materials, and performance. No new issues of safety or effectiveness have been raised.