



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 25, 2016

Stryker Corporation
Division: Stryker Instruments
Kim Wiersema
Staff Regulatory Affairs Specialist
4100 E. Milham Ave
Kalamazoo, Michigan 49001

Re: K153407
Trade/Device Name: Neptune 3 Waste Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX, FYD
Dated: March 23, 2016
Received: March 24, 2016

Dear Kim Wiersema:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
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Enclosure

Indications for Use

510(k) Number (if known)

K153407

Device Name

Neptune 3 Waste Management System

Indications for Use (Describe)

The Neptune 3 Waste Management System is intended to be used in the operating room, pathology, surgical centers and doctor's offices to collect and dispose of surgical fluid waste as well as collect smoke generated from electrocautery or laser devices.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5 – 510(k) Summary

Prepared: 22 April 2016

I. SUBMITTER

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
Phone: 269-323-7700

Contact: Kim Wiersema

II. DEVICE

Name of Device:	Neptune 3 Waste Management System
Common/Usual Name:	Portable suction and smoke evacuation device
Regulation Numbers:	21 CFR 878.4780 and 21 CFR 878.5070
Regulation Name:	Powered Suction Pump Apparatus, exhaust, surgical
Regulatory Class:	II
Product Codes:	JCX and FYD

III. PREDICATE DEVICE

Predicate Device	Stryker Neptune 2 Rover, K132671
Reference Devices	Dornoch Ultra Suction System, K133786 Buffalo Filter Porta Plumesafe, K924732 Valleylab OptiMumm Smoke Evacuator System, K980915

IV. DEVICE DESCRIPTION

The Neptune 3 Waste Management System provides fluid waste management, fluid volume measurement and surgical smoke evacuation capabilities and is also equipped with a motorized IV pole. The Stryker Neptune 3 Rover (Model Number 0703-001-000) is a mobile device used to suction and collect waste fluids and evacuate smoke during surgical procedures. The Stryker Neptune 3 Rover collects surgical waste fluid within a closed suction system and is paired with a compatible Stryker Neptune 2 Docking Station (0702-014-000) to facilitate disposal. The Stryker Neptune 3 Rover functions together with existing Neptune 2 components as follows:

Stryker Neptune 2 Manifolds: Product Code: JCX 510k: K132671	Component providing an interface between the Rover and suction tubing along with backflow prevention. May also incorporate specimen collection capability (model dependent).
Fluid Suction High Efficiency Particulate Air (HEPA) Filter: Product Code: JCX 510k: K132671	Component providing filtration of air drawn out of the fluid collection canister.

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Smoke Evacuation Ultra Low Penetration Air (ULPA) Filter: Product Code: FYD 510k: K132671	Component providing filtration of evacuated smoke and air as it passes through the Rover. The filter also provides an interface to connect smoke evacuation accessories (1/4 inch, 3/8 inch, or 7/8 inch).
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V. INDICATIONS FOR USE

The Neptune 3 Waste Management System is intended to be used in the operating room, pathology, surgical centers and doctor’s offices to collect and dispose of surgical fluid waste as well as collect smoke generated from electrocautery or laser devices.

CONTRAINDICATIONS

The Neptune 3 Waste Management System is contraindicated against:

- Connection directly to chest tubes.
- Connection to closed wound drainage systems.

The Indications for Use are identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table identifies technological characteristics shared between the Predicate and Subject device:

	Predicate Device	Subject Device
Indications for Use	Intended to be used in the operating room, pathology, surgical centers, and doctor’s offices to collect and dispose of surgical fluid waste, as well as, collect smoke generated from electrocautery or laser devices.	Same
Contraindications	Contraindicated against <ul style="list-style-type: none"> ▪ Connection directly to chest tubes. ▪ Connection to closed wound drainage systems. 	Same
For use with	<ul style="list-style-type: none"> • Neptune 2 Docking Station • Neptune 2 Manifolds • Stryker HEPA & ULPA Filters • Compatible Smoke Evacuation accessories • Compatible suction tubing and accessories 	Same
Patient Contact	No direct or indirect patient contact	Same

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	Predicate Device	Subject Device
Materials of Construction	Steel, aluminum, glass, insulation, TPE, thermoplastics, printed circuit board assemblies and electronic/wiring components HEPA, ULPA and carbon filter media	Same
Energy Used	120VAC, 60Hz, 12 A	Same
Electrical Isolation Type	Class I, Type CF Applied Part	Same
Electrical Safety & EMC	Tested and compliant with IEC 60601-1, IEC 60601-1-2	Same
Design Features	<p>Suction Characteristics</p> <ul style="list-style-type: none"> • Continuous suction • Two independently operated suction levels • Electronic regulator • Electric pump • HEPA filtration (exhaust) • Low, Medium, High Vacuum Range Indicators <p>Fluid Collection</p> <ul style="list-style-type: none"> • 24L collection capacity • 2 canisters: 1 @ 20L, 1 @ 4L • Fluid volume measurement <p>Smoke Evacuation</p> <ul style="list-style-type: none"> • ULPA filtration • Voltage-controlled motor • Adjustable in 10% increments • Manual and Automatic Modes • 80 hour filter life <p>IV Pole</p> <ul style="list-style-type: none"> • 4 hooks, powered actuation 	Same

The following differences between the subject and predicate device were considered in relation to the substantial equivalence determination:

- Disposables management – the Neptune 3 Rover incorporates RFID technology to authenticate and track manifold use.
- The Neptune 3 Rover incorporates a touchscreen display
- The Neptune 3 Rover has a higher maximum suction setting
- The Neptune 3 Rover incorporates a 4L canister illumination feature
- The available smoke evacuation power range of the Neptune 3 Rover is expanded and provides a wider range of smoke evacuation flow rates

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VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Stryker Neptune 3 Rover. Testing included assessment of RF wireless performance. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern.

Mechanical Testing

Suction Performance

Rover fluid suction flow rate was evaluated simulating an emergent situation when clinicians might need to quickly aspirate fluids to provide surgical site visibility as well as worst case simulated use. Neptune 3 Waste Management System met all identified acceptance criteria, demonstrating passing results.

ISO 10079-1 Electrically-powered suction safety

The Rover was evaluated against the minimum safety and performance requirements for medical and surgical suction equipment as defined in this international standard. Neptune 3 Waste Management System met all identified acceptance criteria, demonstrating passing results.

Smoke Blower Performance

Smoke evacuation minimum and maximum flow rates were evaluated against predetermined acceptance criteria. Neptune 3 Waste Management System met all identified acceptance criteria, demonstrating passing results.

IV Pole Performance

IV pole extension and retraction times were evaluated against predetermined acceptance criteria. Neptune 3 Waste Management System met all identified acceptance criteria, demonstrating passing results.

Docking Performance

Evaluation of the Neptune 3 Rover compatibility with the Neptune 2 Docking Station included demonstration of waste off-load after worst-case clinical use conditions. The Neptune 3

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Waste Management System met all identified acceptance criteria, demonstrating passing results.

ULPA Filtration

Evaluation of the Neptune 3 Rover compatibility with the Neptune 2 ULPA filter included evaluation of UPLA rating in accordance with IEST-RP-CC007 under worst case flow and vacuum conditions. Neptune 3 Waste Management System met identified acceptance criteria, demonstrating passing results.

Human Factors Evaluation

Human factors analysis and usability testing was performed in support of the Substantial Equivalence determination and in accordance with FDA’s Guidance for Industry and FDA Staff, “Applying Human Factors and Usability Engineering to Optimize Medical Device Design” and IEC 62366-1 “Medical Devices – Application of Usability Engineering to Medical Devices.”

Biocompatibility

Biocompatibility data is not required to support a Substantial Equivalence determination as the Neptune 3 Rover is identical to the predicate device in that there are no components with direct or indirect patient contact.

Animal Study

Not Applicable – data from animal studies was not provided to support the Substantial Equivalence determination. Animal studies are not required to demonstrate safety or feasibility of the Neptune 3 Rover.

Clinical Studies

Not Applicable – data from clinical studies was not provided to support the Substantial Equivalence determination. Clinical studies are not required to demonstrate safety or feasibility of the Neptune 3 Rover.

VIII. CONCLUSIONS

The differences that exist between the Neptune 3 Rover and its predicate do not raise different questions of safety or effectiveness. The results of non-clinical performance testing demonstrate that the Neptune 3 Rover will perform as intended and is substantially equivalent to the predicate device.