K132671

DEC 20 2013

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Kalamazoo, MI 49001
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Instruments

510(k) Summary

510(k) Owner:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-389-3549 (f) 269-389-5412
Contact Person:	Michelle Jump
Registration No.:	1811755
Trade Name:	Stryker® Neptune 2 Waste Management System
Common Name:	Portable suction and smoke evacuation device
Classification Name and Regulation Number	**Primary Product Code** **Secondary Product Code**
Predicate Devices:	Stryker® Neptune Waste Management System (K012991) Dornoch Transposal Ultra System (K081047) Valleylab OptiMumm Smoke Evacuator System (K980915)

Primary Product Code

Product Code	Device	Regulation Number	Class
JCX	apparatus, suction, ward use, portable, ac-powered	21 CFR 872.4780	II

Secondary Product Code

Product Code	Device	Regulation Number	Class
FYD	apparatus, exhaust, surgical	21 CFR 878.5070	II

<table>
<tr><td>Device Description:</td><td>The Neptune 2 Waste Management System is a fluid waste management system with smoke evacuation. It collects surgical waste fluid within a closed suction system, then disposes of it through a docking station. The system is comprised of a rover and a docker (also referred to as a docking station).

The Neptune 2 Rover (Model Number: 0702-001-000) is a mobile, AC-powered surgical fluid waste collection device. It is intended to collect waste fluids and evacuate smoke during surgical procedures.

The Neptune 2 Docking Station (Model Number: 0702-014-000) is a stationary device for automated rover cleaning and waste offloading. It provides a fixed connection to the hospital's water supply, sewer, and electricity.

The following Stryker accessories are for use with the Neptune 2 Waste Management System:

<table>
<tr><th>Model Number</th><th>Product Name</th></tr>
<tr><td>0700-001-026</td><td>Neptune Docking Detergent</td></tr>
<tr><td>0702-020-000</td><td>Neptune 2 4-Port Manifold</td></tr>
<tr><td>0702-020-001</td><td>Neptune 2 Specimen Collection 4-Port</td></tr>
<tr><td>0702-025-000</td><td>Neptune 2 Single-Port Manifold</td></tr>
<tr><td>0702-034-000</td><td>Fluid Suction HEPA Filter</td></tr>
<tr><td>0702-040-000</td><td>Smoke Evacuator ULPA Filter</td></tr>
<tr><td>0702-045-023</td><td>Smoke (Evacuator)Tubing, 3/8 inch x 10 feet</td></tr>
<tr><td>0700-026-000</td><td>Smoke (Evacuator) Tubing, 7/8 inch x 10 feet</td></tr>
<tr><td>0702-045-027</td><td>PenAdapt®</td></tr>
</table>
</td></tr>
<tr><td>Indications for Use:</td><td>The Neptune 2 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.</td></tr>
<tr><td>Contraindications</td><td>The Neptune 2 Waste Management System is contraindicated against:

• Connection directly to chest tubes.
• Connection to closed wound drainage systems.</td></tr>
<tr><td>Testing</td><td>The Neptune 2 Waste Management System meets the specification and performance characteristics as identified in Stryker's internal design control procedures. Bench testing was performed to demonstrate the performance of the device. Testing was completed to verify and validate the device as outlined in the device description. Testing included electrically powered suction safety, electrical safety, vacuum cycling, software, smoke evacuation and filtration. Human factors analysis and usability testing was performed on the user interface, labeling, and training materials.</td></tr>
<tr><td>Biocompatibility</td><td>Biocompatibility testing of the Neptune 2 Waste Management System confirmed that the device meets the applicable requirements of the FDA Blue Book Memorandum G95-1 entitled Use of International Standards ISO-10993 Biological Evaluation of</td></tr>
</table>

	Medical Devices Part -1: Evaluation and Testing and are biocompatible.
Substantial Equivalence (SE) Rationale:	The Neptune 2 Waste Management System, when compared to its predicates, has an equivalent intended use, protocols for use, mode of operation, technological characteristics and performance specifications. (See attached Table 1: Device Comparison Matrix)
Safety and Effectiveness:	Based upon the comparison to the predicate devices, the Stryker Neptune 2 Waste Management System is substantially equivalent to the predicate devices.
Submitted by:	Michelle Jump Associate Regulatory Affairs Analyst Signature
Date Submitted:	December 20, 2013

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Table 1: Device Comparison Matrix

	Stryker Neptune 1	Dornoch Transposal Ultra	Covidien (Valleylab) OptiMumm	Stryker Neptune 2
Model Number	Rover: 0700-010-00	Duo: DU100 Quad: QD100	OptiMumm: 945 102 097	Rover: 0702-010-000
Clearance				
510k	K012991	K081047	K980915	Pending
Classification	II	II	II	II
Regulation	21 CFR 878.5070	21 CFR 878.4780	21 CFR 878.5070	21 CFR 878.4780 21 CFR 878.5070
Product Code	FYD	JCX	FYD	JCX FYD
Indications for Use	The Neptune Waste Management system is intended to be used in the Operating Room, 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.	The Dornoch Transposal Ultra System is self-powered suction / vacuum pump intended to collect and dispose of liquid waste within Hospital Operating Rooms, Pathology Labs, Surgical Outpatient Centers, and Doctor's Offices.	The Indications for Use of the Valleylab OptiMumm Smoke Evacuator system are for the removal of smoke and incidental fluids produced during electrosurgery and/or laser surgery. The removal of smoke from the surgical site improves visibility and reduces potential health hazards associated with surgical smoke.	The Neptune 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.

Contraindication	None	None	None	The Neptune 2 Waste Management System is contraindicated against: • Connection directly to chest tubes. • Connection to closed wound drainage systems.

System Configuration

Size	18 x 25 x 51"	24" x 24" x 55" or 23" x 33" x 55" (depending on model)		19 x 23 x 70"
Casters	5" swiveling hospital grade casters	4" swiveling casters		5" swiveling hospital grade casters
Bumpers	Rubber bumpers	Plastic bumpers		Rubber bumpers
Cleaning instructions	Wipe the surfaces of the Rover and Docking Station with general purpose disinfectant. **Caution against using Cidex® or similar cleansers.**	Wipe down the cart with a hospital approved bleach wipe (Sani-Cloth Bleach Germicidal wipe, Clorox: Germicidal Wipes or equivalent). **Caution against using non-approved wipes.**		Wipe the external surfaces of the rover with a soft, lint-free cloth moistened with a non-abrasive, hospital disinfectant prepared according to the manufacturer's instructions. **Caution against using solvents, lubricants, or other chemicals, including glutaraldehyde or similar chemical cleaners.**
Rover is battery-powered during docking	Yes	No		No
# of canisters	1	2 or 4 (depending on model)		2
Volume measurement with digital display	Yes	Yes		Yes

Offloading and canister cleaning accessory	Neptune 1 Docking Station (0700-005-000)	Ultra Evac Docking Station UL-EV100		Neptune 2 Docking Station (0702-014-000)
Rover empty weight	230 lbs	195 lbs or 225 lbs (depending on model)		300 lbs
Electrical isolation type	Class I, Type CF Applied Part	Information not available		Class I, Type CF Applied Part
Enclosure protection	IPX0 Ordinary Equipment	Information not available		IPX0 Ordinary Equipment
120V single phase electric power requirements	16 A	4.5 A		12 A
Number of uses before docking	Limited by fluid capacity	Limited to 2 or 4 procedures (depending on model)		Limited by fluid capacity
User display	LCD screen	LCD screen		LCD screen
Docking Station				
User interaction to dock	Push rover into docker	Push Rover adjacent to Docker and Insert docker's gas-pump-style nozzle into rover		Push rover into docker
Waste/water connection to rover	Dry-break hydraulic couplings	Information not available		Dry-break hydraulic couplings
Rover-docker coupling size	.875" body diameter	.625" OD		1.325" body diameter
Rover-docker coupling orientation	Horizontal	Approximately 25° from horizontal		Vertical
Water inlet control	Solenoid valve	Solenoid valve		Solenoid valve
Backflow prevention valve	Internal	External		Internal
Weight	90 lbs	100 lbs		95 lbs
Waste/water connection to facility	Quick disconnect fittings	Information not available		Quick disconnect fittings

120V single phase electric power requirements	3 A	15 A		3 A
Rover-Docker Communication	Infrared	Electrical contacts		Infrared
Offloads waste to sanitary sewer	Yes	Yes		Yes
Rinses canister with facility water	Yes	Yes		Yes
Canister cleaning method	Sprinkler	Sprinkler		Sprinkler
Canister cleaning detergent	Neptune docking detergent (0700-001-026)	Ultra Enzyme (UL-EZ200) and Bleach		Neptune docking detergent (0700-001-026)
Electromagnet for holding rover to docker	Yes	No		Yes
Docker dimensions	25" x 20" x 22"	20" x 16" x 28"		23" x 23" x 16"
Docker supports	Casters with adjustable extensions	Information not available		Fixed rubber pads
Vacuum System				
Vacuum control range	254 - 483 mm-Hg	14 - 700 mm-Hg		50 - 480 mm-Hg
Suction filtration efficiency	HEPA	HEPA		HEPA
Vacuum limit adjustable	Yes	Yes		Yes
Simultaneous levels of suction	1	2		2
Optional wall suction ports	Yes	Yes		Yes
Canister vacuum indicator	Analog gauge (mm-Hg, in-Hg)	Digital display (mm-Hg)		Digital display (mm-Hg)

Canister vacuum level regulation	Mechanical regulator	Electronic regulator		Electronic regulator
Collection Canisters				
Rover canister capacity	20 L	33 L or 52 L (depending on model)		24 L
Canister graduation label	Yes	Yes		Yes
Electronic canister overfill protection	Yes	Yes		Yes
Mechanical canister overfill protection	Float-style shut-off valve in rover	Hydrophobic filter located in disposable canister lid.		Float-style shut-off valve in rover
Volume display accuracy	± 175 mL	± 150 mL		± 150 mL , ± 50 mL (20 L canister, 4 L canister)
Volume display resolution	50 mL	10 mL		50 mL, 20 mL (20 L canister, 4 L canister)
Lighted canister contents	No	Yes		No
Smoke Evacuator				
Filtration efficiency	HEPA		ULPA	ULPA
Maximum flow rate	33 CFM		20 CFM	24 CFM
Minimum flow rate	0 CFM		3 CFM	21 CFM
Maximum Suction Range (100% power)	61 mm-Hg		99 mm-Hg	67 mm-Hg
Minimum suction range (20% power)	0 mm-Hg		12 mm-Hg	34 mm-Hg
Pre-filter	Single-use disposable		Single-use disposable	Multi-use disposable
Filter life indicator	Yes		Yes	Yes
Variable speed settings	Infinite (continuous rotary dial)		5	9

Filter life	120 hrs		25 hrs	80 hrs
Automatic activation	Yes		Yes	Yes
# of port sizes	1		1	3
Disposable tubing sizes	7/8"		3/8", 7/8"	3/8", 7/8"
Disposable cautery pencil attachment	Yes		Yes	Yes
Tubing/attachment sterility	EO		Information not available	EO
Tubing/attachment biocompatibility	ISO 10993-1		ISO 10993-1	ISO 10993-1
Manifold				
Insertion direction	Vertical	45 degree		Horizontal
Port size (outer diameter)	.375"	2x .320" and 1x .375"		.375"
Use restrictions	Single patient use	Single patient use		Single patient use
Suction port quantity	1-port or 4-port	3-port		1-port or 4-port
Pathology specimen collector	Yes	Yes		Yes
Weight (size)	4.7 oz	3.1 oz		1.6 oz
Sterility	Non-sterile	Non-sterile		Non-sterile
IV Pole				
Powered actuation	Yes	Yes		Yes
Actuation method	Electric motor-driven	Information not available		Electric motor-driven
# of hooks	2	2		4

Travel	29 in	Information not available		32 in
Maximum height from floor	89 in	Information not available		102 in
Environmental Conditions				
Operation Temp	10 - 40°C	10 - 40°C	Information not available	10 - 40°C
Operation Humidity	30 - 75%	30 - 75%	Information not available	30 - 75%
Operation Barometric Pressure	700 - 1060 hPa	700 - 1060 hPa	Information not available	700 - 1060 hPa
Storage / Transportation Temp	-20 - 40°C	-20 - 40°C	Information not available	-20 - 40°C
Storage / Transportation Humidity	10 - 75%	10 - 75%	Information not available	10 - 75%
Storage / Transportation Barometric Pressure	500 - 1060 hPa	500 -1060 hPa	Information not available	500 - 1060 hPa

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 20, 2013

Stryker Corporation
Michelle Jump, RAC, M.S.
Regulatory Affairs Associate Analyst
4100 E. Milham Ave,
KALAMAZOO MI 49001

Re: K132671
Trade/Device Name: Neptune 2 Waste Management System
Regulation Number: 21 CFR 872.4780
Regulation Name: Apparatus, suction, ward use, portable, ac-powered
Regulatory Class: II
Product Code: JCX, FYD
Dated: November 14, 2013
Received: November 15, 2013

Dear Ms. Jump:

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.

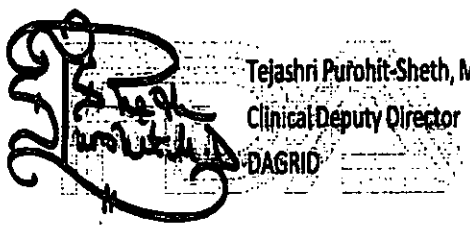
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K132671

Device Name: Stryker® Neptune 2

Indications for Use

The Neptune 2 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.

Prescription Use ___X___ and/or Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S
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