August 23, 2021

Aatru Medical, LLC
James Rogers
Regulatory Affairs and Quality Assurance
1301 East 9th Street, Suite 2700
Cleveland, Ohio 44114

Re: K201400
Trade/Device Name: npSIMS Negative Pressure Surgical Incision Management System™ (npSIMS)™
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-Powered Suction Apparatus Device Intended For Negative Pressure Wound Therapy
Regulatory Class: Class II
Product Code: QPX
Dated: June 22, 2021
Received: July 1, 2021

Dear James 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,

Lixin Liu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201400

Device Name
npSIMS Negative Pressure Surgical Incision Management System™
npSIMS™

Indications for Use *(Describe)*

The Negative Pressure Surgical Incision Management System (npSIMS)™ is indicated for patients who may benefit from wound management via application of negative pressure, as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The npSIMS is indicated for removal of small amounts of exudate from closed surgical incisions.

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 K201400

Prepared in conformance with 21CFR 807.92

Submitter	Aatru Medical, LLC. 1301 East Ninth Street, Suite 2700 Cleveland, Ohio 44114 http://www.aatru.com
Contact Person	Primary Contact James Jochen Rogers Regulatory Affairs and Quality Assurance jr@aatru.com T: 216-303-6063
Date Prepared	August 16, 2021
Trade Name(s)	npSIMS Negative Pressure Surgical Incision Management System™ npSIMS™
Classification	Regulation Number: 21 CFR 878.4683 Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy. Regulatory Class: Class II Product Code/Panel: QPX/General and Plastic Surgery Devices
Predicate Device Reference Device	K151710 Spiracur SNaP Wound Care System K180698 Smith & Nephew Medical PICO7 Single Use Negative Pressure Wound Therapy System
Device Description	The npSIMS Negative Pressure Surgical Incision Management System™ by Aatru Medical, LLC is a single-use medical device consisting of a non-sterile vacuum chamber and sterile dressing and tubing kit. The npSIMS is intended for use with closed incisions with low exudate up to 10ml, or over a period of up to 7 days. The disposable vacuum chamber initially generates a peak negative pressure of -100±5mmHg at the wound surface, and maintains a continuous, linear rate of pressure decline to -60mmHg over 7 days (nominally, 80mmHg ± 20mmHg). Wound exudate is managed by the absorptive dressing technology. The tubing can be cut to length based upon patient needs. Making use of a fully pre-assembled wound contact dressing, the npSIMS operates silently without the use of an external electromechanical pump nor collection canister, enabling discrete patient portability. The duration of treatment is dependent upon the recommendation of the treating physician. After use, all components of the npSIMS are disposed of as clinical waste in accordance with local protocols and regulations.
Indication for Use	The Negative Pressure Surgical Incision Management System (npSIMS)™ is indicated for patients who may benefit from wound management via application of negative pressure, as the device may promote wound healing through the removal of excess exudate, infectious material, and tissue debris. The npSIMS is indicated for removal of small amounts of exudate from closed surgical incisions.

Technological Characteristics Comparison	Subject Device: npSIMS Negative Pressure Surgical Incision Management System™ K201400	Predicate Device: Spiracur SNaP Wound Care System K151710
Regulation	Regulation Number: 21 CFR 878.4683 Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy. Regulatory Class: Class II	Regulation Number: 21 CFR 878.4683 Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy. Regulatory Class: Class II
Classification	Product Code/Panel: QPX/General and Plastic Surgery Devices	Product Code/Panel: OKO/General and Plastic Surgery Devices
Indications for Use	The Negative Pressure Surgical Incision Management System (npSIMS)™ is indicated for patients who may benefit from wound management via application of negative pressure, as the device may promote wound healing through the removal of excess exudate, infectious material, and tissue debris. The npSIMS is indicated for removal of small amounts of exudate from closed surgical incisions.	The SNaP® Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
Negative pressure power source – vacuum generating element	Non-powered negative pressure suction generated by oxygen scavenger	Non-powered negative pressure suction generated by mechanical spring
Negative Pressure Range (high to low)	Negative pressure between 100mmHg and 60mmHg.	75mmHg ± variable 100mmHg ± variable 125mmHg ± variable
Exudate management	Use with low exudate wounds up to 10ml	Use with wounds with low to moderate exudate up to 60ml
Wear time (Duration of use)	Up to 7 days	Up to 7 days

Technological Characteristics Comparison	Subject Device: npSIMS Negative Pressure Surgical Incision Management System™ K201400	Predicate Device: Spiracur SNaP Wound Care System K151710
Wound interface elements	Dressing construction: • Absorbent wound dressing • Silicone gasket • Nominal Pad Size: 3.5x14 cm (1.4x5.6 in) • Overall Size: 11.6x22.6 cm (4.6x8.9 in)	Dressing construction: • Occlusive drape with optional foam interface; • Hydrocolloid adhesive • Overall Size: 10x10cm (2.9x2.9 in) to 15x15cm (5.91x5.91 in)
Tubing Material	Polyvinyl Chloride Elastomer	Polyvinyl Chloride Elastomer
Indicators of System Status	Indicators: • Slight warming of vacuum chamber • Dressing has taut appearance and firmness to touch. • Blue sealing flap on top of vacuum chamber is slightly depressed in the vacuum chamber activation slot. • Visual change of dressing; • Dressing saturation is evident when fluid color permeates the entire dressing or is evident in the tubing	Indicators: • Green capacity indicator moving on side of canister • Dressing has a sucked down appearance and feels hard to the touch. • Green capacity indicator is visible and stationary. • Visual change as dressing becomes flaccid. Red discharge indicator is visible in cartridge. • Dressing saturation is evident when fluid color permeates entire dressing.
Sterility; Method of Sterilization	Yes Ethylene Oxide	Yes Radiation
Performance Data - discussion of non-clinical tests	The npSIMS Negative Pressure Surgical Incision Management System™ is designed to, complies with, and has been tested as part of verification and validation activities to, the FDA Recognized Consensus Standards listed in the table below, as applicable to device features and components:	

Requirement	Reference #	Title
Biocompatibility – Physical/Chemical Information	ANSI AAMI ISO 10993-1:2018 ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
Biocompatibility – Cytotoxicity	ANSI AAMI ISO 10993-5:2009/R2014	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
Biocompatibility – Sensitization - Irritation or Intracutaneous Reactivity	ANSI AAMI ISO 10993-10:2010/R2014 ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Technological Characteristics Comparison	Subject Device: npSIMS Negative Pressure Surgical Incision Management System™ K201400		Predicate Device: Spiracur SNaP Wound Care System K151710
	Biocompatibility – Implantation Effects	ISO 10993-6 Third edition 2016-12-01	Biological evaluation of medical devices -- Part 6: Tests for local effects after after implantation
	Biocompatibility - Material Mediated Pyrogenicity - Acute Systemic Toxicity - Subacute / Subchronic Toxicity	ANSI AAMI ISO 10993-11: 2017 ISO 10993-11 Third edition 2017-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	Sterility	ISO 11135:2014 + A1:2018	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
	Packaging	ASTM D4169-16: 2016	Standard Practice for Performance Testing of Shipping Containers and Systems
	Usability	BS EN 62366-1: 2015 + A1:2020 ANSI AAMI IEC 62366-1:2015 + AMD1:2020 IEC 62366-1 Ed. 1.1: 2020-06	Medical devices: Part 1: Application of usability engineering to medical devices
	In vitro performance tests of the npSIMS Negative Pressure Surgical Incision Management System™ were carried out to evaluate its ability to meet product performance specifications, including delivery of negative pressure, wound exudate fluid management, and system performance. The test results met all acceptance criteria and ensure the design and construction are suitable for its intended use and as recommended by the Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT) - Class II Special Controls Guidance for Industry and FDA Staff.		
Statement of Substantial Equivalence	Based upon technological characteristics, safety and performance testing, and conformance with voluntary standards, the npSIMS Negative Pressure Surgical Incision Management System™ by Aatru Medical, LLC is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.		