May 26, 2020

Guard Medical Inc.
% Eric Bannon
Consultant
AlvaMed, Inc.
935 Great Plain Avenue, #166
Needham, Massachusetts 02492

Re: K200305
Trade/Device Name: NPseal
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: OKO
Dated: May 1, 2020
Received: May 4, 2020

Dear Eric Bannon:

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,

Anjana Jain, 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)*
K200305

Device Name
NPseal

Indications for Use *(Describe)*
The NPseal is indicated for patients who would benefit from wound management via application of negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudates 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.

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

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510(K) SUMMARY

I. SUBMITTER

Guard Medical, Inc.
10 East 40th
Street Suite 3310
New York, NY 10016

Phone: (888) 417-3644
Fax: (617) 249-0955

Contact Person: Eric Bannon

Date Prepared: May 18, 2020

II. DEVICE

Name of Device: NPseal

Common or Usual Name: Negative Pressure Wound Therapy Non-powered Suction Apparatus

Classification Name: Non-Powered suction apparatus device intended for negative pressure wound therapy. (21 CFR 878.4683)

Regulatory Class: II

Product Code: OKO

III. PREDICATE & REFERENCE DEVICES

Predicate Device: SNaP Wound Care System, K151710

Reference Device: PICO Single Use Negative Pressure Wound Therapy System, K180618

IV. DEVICE DESCRIPTION

The NPseal Negative Pressure Advanced System is a single-use device that includes an integrated, mechanical pump system. The NPseal maintains Negative Pressure Wound Therapy (NPWT) in the -75 mmHg to -125 mmHg nominal range.

The NPseal is intended for 3 days of use. Therapy duration of the system may be less than indicated if clinical practice or other factors such as wound size, rate or volume of exudate, or orientation of the dressing results in earlier removal or need for system change. The NPseal can be replaced only one time for a total maximum wear time of 6 days.

The NPseal is intended for surgically closed incisions up to 5 cm × 0.5 cm.

V. INDICATIONS FOR USE

The NPseal is indicated for patients who would benefit from wound management via application of negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudates from closed surgical incisions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

	Subject Device: **NPseal**	**Predicate Device:** **SnaP Wound Care System**	**Reference Device:** **PICO Single Use Negative Pressure Wound Therapy System**
Manufacturer	Guard Medical	Spiracur	Smith & Nephew
510(k) Number	K200305	K151710	K180618
Product Code	OKO	OKO	OMP
Regulation Number	878.4683	878.4683	878.4780
Regulation Description	Non-Powered suction apparatus device intended for negative pressure wound therapy	Non-Powered suction apparatus device intended for negative pressure wound therapy	Powered suction pump
Common Name	Negative Pressure Wound Therapy non-powered suction apparatus	Negative Pressure Wound Therapy non-powered suction apparatus	Powered suction pump and wound dressing kit

	Subject Device: **NPseal**	**Predicate Device:** **SnaP Wound Care System**	**Reference Device:** **PICO Single Use Negative Pressure Wound Therapy System**
Intended Use	The NPseal is indicated for patients who would benefit from wound management via application of negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudates 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.	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include: - Chronic - Acute - Traumatic - Subacute and dehisced wounds - Partial-thickness burns - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed surgical incisions PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.
Sterility	Sterile – Gamma irradiation	Sterile – Gamma irradiation	Sterile – EO
Single Use	Yes	Yes	Yes
Wear Time	3 days	7 days	7 days
Dressing film(s)	High Moisture Vapor Transmission Rate (MVTR), breathable polyurethane film	Single layer hydrocolloid dressing, non-breathable	High Moisture Vapor Transmission Rate (MVTR) upper film, perforated silicone adhesive skin layer

	Subject Device: **NPseal**	**Predicate Device:** **SnaP Wound Care System**	**Reference Device:** **PICO Single Use Negative Pressure Wound Therapy System**
Negative Pressure Operating Ranges	-75 to -125 mmHg	-75, -100, or -125 mmHg	-80 mmHg

The subject, predicate and reference devices are all NPWT dressing systems.

The subject and predicate devices are substantially equivalent, as evidenced by their shared characteristics:

- Single use
- Nonpowered
- Identical negative pressure operating ranges (-75 to -125 mmHg)
- Indicated for removal of small amounts of exudates.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the NPseal was conducted in accordance with the international standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA along with the agency’s guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process:' Guidance for Industry and Food and Drug Administration Staff" (issued June 16, 2016). The tests performed included the following:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Subacute Systemic Toxicity
- Subchronic Systemic Toxicity
- Implantation

Bench Testing

- Pressure and exudate handling over time test
- Curved surface pressure over time
- Foam characterization test
- Pump body adhesion test
- Dressing peel test
- Exudate handling without negative pressure test
- Moisture vapor transmission rate (MVTR) test

- Shelf Life test
- Benchtop Usability Verification
- Set Negative Pressure test

Human Factors Testing

- User validation study

VIII. CONCLUSIONS

The test data support the safety of the device and the hardware verification and validation demonstrate that the NPseal shall perform as intended in the specified use conditions. The data demonstrate that the NPSeal is substantially equivalent to the predicate device with respect to the intended use and technological comparison. There were no new questions regarding safety or effectiveness.