



February 10, 2022

Guard Medical Inc
% Eric Bannon
VP of Regulatory Affairs
Alvamed Inc
935 Great Plain Ave, Suite 166
Needham, Massachusetts 02492

Re: K212971

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: January 7, 2022

Received: January 11, 2022

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,

Julie Morabito, Ph.D.
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

Indications for Use

510(k) Number (if known)
K212971

Device Name
NPseal

Indications for Use (Describe)

The NPseal is indicated for patients who would benefit from wound management via application of a 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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1.0 TRADITIONAL 510(K) SUMMARY K212971

This Traditional 510(k) for the NPseal is submitted based on the FDA Guidance document "Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and Food and Drug Administration Staff" (issued September 13, 2019).

1.1 Name and Address of Sponsor

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1.2 Correspondent/Primary Contact Person

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1.3 Submission Information

Date Summary Prepared:	September 16, 2021
Name of Device:	NPseal
Common or Usual Name:	Negative Pressure Wound Therapy Non-Powered Suction Apparatus
Classification:	Class II
Product Code:	OKO (21 CFR 878.4683)
Predicate Device:	NPseal (K211130)

1.4 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 6 days of use. Therapy duration of the system may be less than indicated if clinical practice or other factors such as time to wound closure and rate of

exudate, result 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 Small is intended for surgically closed incisions up to 5cm x 0.5 cm

The NPseal Medium is intended for surgically closed incisions up to 10 cm x 0.5 cm.

The NPseal Large is intended for surgically closed incisions up to 15 cm x 0.5 cm.

1.5 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.

1.6 Comparison of Manufacturer's Cleared Device and Modified Device

Table 1. Comparison of Subject Device to Cleared Device

	<u>Subject Devices</u> NPseal Medium NPseal Large	<u>Predicate Device</u> NPseal Small
510(k) Number	K212971	K211130
510k Submitter/Holder	Same as predicate	Guard Medical
Product Code	Same as predicate	OKO
Regulation No.	Same as predicate	878.4683
Regulation Description	Same as predicate	Non-Powered suction apparatus device intended for negative pressure wound therapy
Common Name	Same as predicate	Negative Pressure Wound Therapy non-powered suction apparatus
Indications for Use	Same as predicate	The NPseal is indicated for patients who would benefit from wound management via application of a negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudates from closed surgical incisions.
Wound types	Same as predicate	Closed surgical incisions
Incision sizes	NPseal Medium: Up to 10 cm x 0.5 cm NPseal Large: Up to 15 cm x 0.5 cm	Up to 5 cm x 0.5 cm

	<u>Subject Devices</u> NPseal Medium NPseal Large	<u>Predicate Device</u> NPseal Small
Single Use	Same as predicate	Yes
Negative Pressure Range	Same as predicate	-75 to -125 mmHg (\pm 17.5 mmHg)
Device Technology	Same as predicate	Nonpowered, integrated pump manually actuated to generate negative pressure. Multilayer pad composed of hydrophilic foam with high fluid absorbency and top breathable film designed to collect and move exudate away from the wound bed.
Management of Exudates	Same as predicate	Managed by the dressing itself – via combination of absorption into the foam pad and evaporation through the breathable upper film.
Materials	Same as predicate	Film: Polyurethane coated with adhesive acrylic, Pad: Hydrophilic polyurethane, Pump: Thermoplastic elastomer
Maximum therapy time	Same as predicate	6 days
Maximum number of dressing changes	Same as predicate	1 dressing change
Wear Time per dressing	Same as predicate	Up to 6 days
Sterility	Same as predicate	Sterile – Gamma irradiation
Biocompatibility	Same as predicate	Complies with ISO 10993-1

1.7 Summary of Modification

The dimensions of the current NPseal device cleared in K200305 and K211130 (NPseal Small) is 11 x 8 cm for use on closed surgical incisions up to 5 cm in length and 0.5 cm in width. The corresponding foam pad size is 7.5 x 4.5 cm.

The subject devices are two longer versions of the NPseal Small:

- The NPseal Medium is 16 x 8 cm with a 12.65 x 4.65 cm foam pad for use on closed surgical incisions up to 10 cm in length and 0.5 cm in width.

- The NPseal Large is 21 x 8 cm with a 17.65 x 4.65 cm foam pad for use on closed surgical incisions up to 15 cm in length and 0.5 cm in width.

All other dimensions including the foam thickness, as well as the pump system and device materials remain identical to the NPseal Small predicate.

1.8 Summary of Functional and Performance Testing

The NPseal dressing length increase for the NPseal Medium and Large was assessed based on risk and the Design Controls in 21 CFR 820.

The following verification and validation testing was performed exclusively on the NPseal Large as it represents the worst-case device size:

- Pressure and Exudate Handling Over Time: Demonstrated that negative pressure could be maintained, the device was capable of absorbing simulated exudate and the volume of simulated exudate absorbed covered less than 50% of the foam pad.
- Benchtop Usability Testing: Demonstrated that usability requirements including pump actuation, device removal from packaging, device application and ability to generate negative pressure met acceptance criteria.
- Packaging Validation: Demonstrated that sterile packaging seal was maintained after undergoing environmental conditioning and simulated distribution.

1.9 Summary of Clinical Testing

No clinical testing was applicable to this submission.

1.10 Conclusion

The NPseal Medium and NPseal Large have been shown to be as safe as the predicate device through bench testing. Size increases made to the device demonstrate substantial equivalence to the predicate device, NPseal Small. Functional and performance testing data demonstrate the substantial equivalence of the NPseal Medium and Large to the NPseal Small (K211130).