October 14, 2025

Rapid Nexus Nanotech Wound Solutions, Inc.
℅ Denise Holliday
Sr. Quality and Regulatory Consultant
Schuler Medical Device
5729 Lebanon Road
Suite 144616
Frisco, Texas 75034

Re: K250115
Trade/Device Name: Hemastyl(™) Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 11, 2025
Received: September 11, 2025

Dear Denise Holliday:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, PhD
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250115

Device Name
Hemastyl(™) Wound Dressing

Indications for Use *(Describe)*
The Hemastyl Wound Gel is indicated for use as follows:

Hemastyl Wound Gel

Rx: Management of wounds such
- 1st degree burns and 2nd degree superficial burns
- stasis ulcers
- pressure ulcers
- diabetic ulcers
- lacerations
- abrasions
- skin tears
- surgical incision sites
- device insertion site wounds
- graft sites
- donor sites

OTC: Management of minor cuts, minor abrasions, minor lacerations and minor scalds.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Notification - Summary

This Traditional 510(k) notification is to provide substantial equivalence for the Rapid Nexus Nanotech Wound Solutions, Inc. Hemastyl™ Wound Dressing, which is substantially equivalent to currently marketed devices intended for wound care.

Submitted by: Rapid Nexus Nanotech Wound Solutions, Inc
830 Challenger Street, Suite 360
Brea, CA 92821
(949) 608-9737

Contact Person: Denise Holliday, Consultant
c/o Schuler Medical Device
5729 Lebanon Road, Suite 144616 Frisco, TX 75034 USA
denise@schulermedicaldevice.com
(469) 268-1865

Device Name: Hemastyl™ Wound Dressing

Date Prepared: July 15th, 2025

Common Name: Amorphous Hydrogel Gel Wound Dressing

Classification Product Code: FRO

Classification: Unclassified

Legally marketed device(s) for substantial equivalence comparison:

Predicate Devices:

AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103)

Reference Devices:

Hyaluronic Acid Topical Wound Cream 0.2%w/w *(K172747)*
Silver Alginate 11 Dressing (K090453)
Puracol Plus Ag Collagen Wound Dressing (K071552)
MedCu Antimicrobial Wound Dressings, Copper-Oxide (MedCu ABWDs) (K180643)

Description of Device: Hemastyl™ Wound Dressing is a repeat use, amorphous hydrogel containing silver chloride (AgCl), cupric chloride (CuCl2) and ferric chloride (FeCl3) as preservatives and HA and fish collagen for use in the management of wounds.

Indications for Use: Rx: Under the supervision of a healthcare professional, Hemastyl™ Wound Dressing is indicated for the management of 1st degree burns and 2nd degree superficial burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

OTC: Hemastyl is indicated for the management of minor abrasions, minor cuts, minor lacerations and minor scalds.

Conditions of Use: The dressing is not intended for the treatment of infected wounds, and cannot be considered to be a substitute for proper management of infections.

CONTRAINDICATIONS: Hemastyl cannot be used on patients who are allergic to fish collagen or silver ions, copper ions, or iron ions. Product use should be discontinued should signs of sensitization occur. The product is not indicated for the treatment of third degree burns.

SUBSTANIAL EQUIVALENCE TABLE

Feature	**Subject Device** Hemastyl® Wound Dressing	**Primary Predicate Device** (Silvasorb) AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B **(K083103)**
Indication for use	**Rx:** Management of wounds such • 1st degree burns and 2nd degree superficial burns • stasis ulcers • pressure. ulcers • diabetic ulcers • lacerations • abrasions • skin tears • surgical incision sites • device insertion site wounds • graft sites • donor sites. **OTC:** Management of minor cuts, minor abrasions, minor lacerations and minor scalds.	**Rx:** Management of wounds such • 1st degree burns and 2nd degree superficial burns • stasis ulcers • pressure. ulcers • diabetic ulcers • lacerations • abrasions • skin tears • surgical incision sites • device insertion site wounds • graft sites • donor sites. **OTC:** Management of minor cuts, abrasions, lacerations and scalds.
Prescription / OTC	Both prescription and OTC	Both prescription and OTC
Physical composition	Hydrogel gel	Hydrogel gel

Mechanism	Works through the release of silver, copper, and iron ions, providing antimicrobial preservation, while the gel matrix maintains a moist wound environment that helps to absorb exudate.	Silver acts as the preservatives during the shelf life.
Antimicrobial agent	The gel contains silver ions, copper ions and iron ions	The gel contains silver ions
Biocompatibility	Biocompatible	Biocompatible
Sterilization	Non-Sterile	Non-Sterile
Principle of Operation	Provide moist environment.	Provide moist environment.
Technology	Incorporate proprietary stabilized silver salt compound to act as the preservative during the shelf life.	Incorporate proprietary stabilized silver salt compound to act as the preservative during the shelf life.
Recommended dressing change	<24 hour	<24 hour
Absorbency	YES	N/A

Hemastyl Wound Dressing and AcryDerm Model #B primarily both incorporate proprietary stabilized silver salt acts as the preservative effectiveness. The gel possesses both moisture donating and moisture sequestering action depending on the moisture level in the wound.

Additionally, Hemastyl™ incorporates elements from MedCu ABWD, Hyaluronic Acid Topical Wound Cream 0.2%w/w, Puracol Plus Ag Collagen Wound Dressing, and Silver Alginate 11 Dressing, for moisture management and product preservation. For more info, please reference the substantial equivalence discussion.

The safety and effectiveness of Hemastyl™ has been validated through biocompatibility testing and performance testing.

Testing Discussion: the new product meets safety and biocompatibility assurance guidelines as provided in the guidance of Part-1 of the ISO standard (Biological Evaluation of Medical Devices) and the NIH Publication 99-4494. The product meets the USP <51> Preservative Assurance Testing requirements for a repeat use product.

The subject device was evaluated through a series of nonclinical tests to demonstrate substantial equivalence to the predicate device. This testing included assessments for cytotoxicity, sensitization, skin irritation, material-mediated pyrogenicity, subacute/subchronic systemic toxicity, and implantation. Additionally, shelf-life testing was conducted to confirm the device maintains its functional integrity and safety throughout the labeled shelf life.

Biocompatibility testing was conducted for this submission in accordance with the US Food and Drug Administration's guidance entitled Use of International Standard ISO‑10993: 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' and test results meet the requirements.

A porcine wound healing study was carried out to evaluate the cytotoxicity of the subject device. The study demonstrated that there were no biologically relevant differences between the subject devices (Hemastyl Gel Wound Dressing), and a Control Silver Antimicrobial Wound Gel (also named SILVASORB GEL®) in terms of wound healing performance characteristics.

All tests met their respective acceptance criteria and confirmed that the subject device is biocompatible and safe for its intended use.

In-vitro Testing: The antimicrobial preservative properties within the Hemastyl™ wound dressing gel have been established by a preservative efficacy test in accordance with the requirements of USP <51 > (Antimicrobial Effectiveness Testing). The biocompatibility of Hemastyl™ has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices).

In-vivo Testing: Product performance has been established using an in-vivo porcine study. The study assessed the dressing performance and compared Hemastyl™ to that of a commercially available equivalent (Silvasorb) AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103), which has a similar formulation to the Hemastyl™. The report findings showed that the rate of wound closure in receipt of Hemastyl™ showed no statistically significant differences when compared to the (Silvasorb) AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103). Wound site adherence, though significant in "Wet to Dry" gauze treated wounds, was not detected for Hemastyl™ or (Silvasorb) AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103) at any point in the study - a reflection of the gel structure of these two devices. Peri-wound inflammation/erythema was less frequently observed and less severe in Hemastyl™ and (Silvasorb) AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103) treated wounds than in similar control "Wet to Dry gauze" treated wounds.

No adverse effects were noted following the use of either Hemastyl™ or the (Silvasorb) AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103) "dressings" investigated.

Manufacturing: The new gel product will be manufactured according to the product specifications and in accordance with good manufacturing practices to ensure the device is safe and effective for their intended uses.

Performance Standards: No performance standards are prescribed for the new product.