September 1, 2023

Jiangsu NewValue Medical Products Co., Ltd.
Lu Wang
Vice Manager
Building G35.the east of KouTai Road and the north of
XinYang Road.CMC.
TaiZhou, Jiangsu 225300
China

Re: K213413
Trade/Device Name: Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 22, 2023
Received: April 7, 2023

Dear Lu Wang:

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,

David Krause -S

David Krause, Ph.D.
Deputy Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Hemostatic Dressing

Indications for Use *(Describe)*

Indications for Use (Rx):
Hemostatic Dressing is intended for the external, temporary control of severely bleeding wounds.

Indications for Use (OTC):
Hemostatic Dressing is intended for temporary external use to stop bleeding of minor wounds, minor cuts and minor abrasions.

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:

Jiangsu NewValue Medical Products Co., Ltd.
Building G35, No.1 Avenue, China Medical City, Taizhou, Jiangsu, 225300, China
Contact Person: Lu Wang
Title: Vice Manager
Tel: 86-015951155167
Email: wanglu@new-value.cn

Summary prepared：08/29/2023

II. DEVICE

Name of Device: Hemostatic Dressing (K213413)
Common Name: Dressing, Wound, Drug
Regulatory Class: II
Product Code: FRO

III. PREDICATE DEVICE

Primary predicate device: HemCon ChitoGauze™ (K090026)

IV. REFERENCE DEVICE

Reference Device: SURECELL® Gelling Fiber Wound Dressing (K173005)

V. DEVICE DESCRIPTION

Hemostatic Dressing is a sterile non-woven fabric dressing composed of hydrophilic fiber (a mixture of chitosan and chitosan derivative). When applied directly over a wound with pressure, this soft and highly absorbent dressing quickly absorbs blood and turns into a gel to seal the wound. It promotes control of wound bleeding and exudates absorption and promotes coagulation.

VI. INDICATIONS FOR USE

Hemostatic Dressing is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Hemostatic dressing Over-the-Counter is indicated for temporary external use to stop bleeding of minor wounds, minor cuts and minor abrasions.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Hemostatic dressing is compared with the predicate device (HemCon ChitoGauze™ (K090026)). The results are shown below in the Technological Characteristics Comparison Table:

Item	**Subject Device Hemostatic Dressing**	**Predicate Device ChitoGauze™ (HemCon Medical Technologies, Inc.)**	**Reference Device SURECELL® Gelling Fiber Wound Dressing**
510(k) number	K213413	K090026	K173005
Classification	Unclassified	Unclassified	Unclassified
Product Code	FRO	FRO	FRO
Common name	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug
Intended use	External hemostatic	External hemostatic	Wound dressing
Indications for use	**Indications for Use (Rx Only)**: Hemostatic Dressing is a hemostatic dressing for the external, temporary control of severely bleeding wounds.	**Indications for Use (Rx Only):** ChitoGauze is a hemostatic dressing for the external, temporary control of severely bleeding wounds.	**Indications for Use (Rx Only):** Under professional medical care, SURECELL™ Gelling Fiber Wound Dressing may be used for the

	Indications for Use (OTC): Hemostatic Dressing is intended for temporary external use to stop bleeding of minor wounds, minor cuts and minor abrasions.	**Indications for Use (OTC):** ChitoGauze is intended for temporary external use to stop bleeding of minor wounds, minor cuts and minor abrasions.	management of leg ulcers (Stage I-IV), pressure ulcers, diabetic ulcers, surgical wounds (e.g. post-operative, donor sites, dermatological), Burns (1st and 2nd degree), surgical or traumatic wounds which have been left to heal by secondary intention. SURECELL™ Gelling Fiber Wound Dressing maintains a moist wound environment. SURECELLTM Gelling Fiber Wound Dressing may also be used for the local management of wounds such as wounds that have been surgically or mechanically debrided, donor sites, and traumatic wounds. **Indications for Use (OTC):** SURECELL™ Gelling Fiber Wound Dressing Over-the-Counter is indicated for minor Burns, minor abrasions and minor Lacerations, minor superficial cuts. SURECELL™ Gelling Fiber Wound Dressing is intended for the maintenance of a moist wound environment.

Duration of Use	Temporary	Temporary	Prolonged exposure
Physical Composition	Single layer needle punched chitosan nonwoven fabric dressing	polyester/rayon blend non-woven medical gauze that is coated with chitosan	Single layer needle punched chitosan nonwoven fabric dressing
Hemostatic Material	A mixture of chitosan and chitosan derivatives	Chitosan	A mixture of chitosan and chitosan derivatives
Mechanism of Action	Hemostatic Dressing will turn into a gel-like condition to absorb the blood and seal the wound. It promotes control of wound bleeding and exudates absorption and promotes coagulation.	ChitoGauze™ will turn into a gel-like condition to absorb the blood. It promotes control of wound bleeding and exudates absorption and promotes coagulation.	SURECELL™ Gelling Fiber Wound Dressing vertically absorbs wound exudate and creates a comfortable clear gel, helps reduce the risk of periwound maceration, maintains a moist environment for optimal wound healing, and removes dead and damaged tissue from wound without damaging newly formed tissue.
Chitosan Form	Needle punched chitosan nonwoven fabric dressing	Chitosan coated on gauze	Needle punched chitosan nonwoven fabric dressing
Single Use	Single Use	Single Use	Single Use
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterilization	Gamma radiation	Gamma radiation	Gamma radiation
Sterility	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}
Primary Packaging	Foil pouch	Foil pouch	Paper-plastic pouch

VIII. NONCLINICAL DATA

To verify that the Hemostatic dressing is as safe and effective as the predicate device, representative samples of Hemostatic dressing were underwent a series of tests including bench testing (absorbency, gelling characteristics, pH, loss on drying, residue on ignition, heavy metals, bacterial endotoxins, packaging sealing, and sterility), biocompatibility testing (cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute toxicity, hemolysis), in-vivo hemostatic, sterilization validation testing, and real-time shelf life stability testing.

IX. CONCLUSION

JIANGSU NEWVALUE Medical PRODUCTS CO.,LTD. considers Hemostatic dressing to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in intended use, design, mechanisms of action, technology and materials. The slight differences between Hemostatic dressing and the predicate devices do not raise any questions of safety and effectiveness.