May 25, 2018

Jiangsu Newvalue Medical Products Co., Ltd
Julie Chen
RA Specialist
Building G35, the east of KouTai Road and the north of Xin Yang Road, CMC.
TaiZhou, 225300 CN

Re: K173005
Trade/Device Name: SURECELL Gelling Fiber Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 10, 2018
Received: April 23, 2018

Dear Julie Chen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K173005

Device Name
SURECELL Gelling Fiber Wound Dressing

Indications for Use *(Describe)*

Rx Indication:

Under professional medical care, SURECELL Gelling Fiber Wound Dressing may be used for the management of : Leg ulcers (Stage I-IV), Diabetic ulcers , Surgical wounds (e.g. post-operative, donor sites, dermatological) ,Pressure ulcers, Burns (1st and 2nd degree), and Surgical or traumatic wounds which have been left to heal by secondary intention.

SURECELL Gelling Fiber Wound Dressing maintains a moist wound environment.

SURECELL 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.

OTC Indication:

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.

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

This 510(K) summary is submitted in accordance with the requirements of 21 CFR Part 807.92

General Information:

Trade/Proprietary Name：	SURECELL™ Gelling Fiber Wound Dressing
Common Name:	Dressing, Wound, Drug
Classification Name:	Unclassified
Product Code:	FRO
Classification:	Unclassified
Submitter/Manufacturer:	JIANGSU NEWVALUE Medical PRODUCTS CO.,LTD. Building G35.the east of KouTai Road and the north of XinYang Road.CMC.TaiZhou.Jiangsu. 225300 Tel: 0523-86867878 Fax: 0523-86867878-8001
Distributor:	Shanghai Newvalue Medical Products Co.,LTD. RM.601,BLDG.2, Leed Platinum Center, NO.1158 Zhangdong Road, Shanghai. 201203 Tel: (86-21)5021 1200 Fax: (86-21)5021 3075
	Contact Person: Julie Chen Title: RA Specialist Tel: (86-21)5021 1200 * 201 Fax: (86-21)5021 3075
	Summary prepared：08/10/2017

510(K) Summary

Device: SURECELL™ Gelling Fiber Wound Dressing

Predicate Device: MedTrade Products AQUANOVA Super-Absorbent Dressing (K070175)

I. DEVICE DESCRIPTION

SURECELL™ Gelling Fiber Wound Dressing is a sterile non-woven wound dressing composed of hydrophilic fiber (a mixture of chitosan and chitosan derivatives). This soft and highly absorbent dressing vertically absorbs wound exudate and creates a comfortable clear gel to maintain a moist environment for optimal wound healing.

II. INDICATIONS FOR USE

Rx Indication:
Under professional medical care, SURECELL™ Gelling Fiber Wound Dressing may be used for the 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.

SURECELL™ 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.

OTC Indication:
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.

III. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device, SURECELL™ Gelling Fiber Wound Dressing, and, predicate device, MedTrade Products AQUANOVA Super-Absorbent Dressing, have same intended use, which is intended for prescription use in the management of chronic wounds, postoperative wounds and traumatic wounds, and, is intended for over-the-counter use for minor burns, minor superficial cuts, minor lacerations and minor abrasions.

The design of subject and predicate devices is highly absorbent, single layer, non-woven dressing. The dressings is cut to the appropriate size flat or folded to the appropriate size flat rope, and individually packed in a pouch. The pouched dressing is terminally sterilized by gamma irradiation to a sterility assurance level SAL of 10^{-6}.

Highly absorbent dressing forms a soft and clear gel upon contact with wound exudate is technological principle for SURECELL™ Gelling Fiber Wound Dressing and predicate device. This technological principle is based on the natural property of the material, which is absorbent chitosan.

The main slightly differences between subject and predicate devices are material. The material of SURECELL™ is chitosan and chitosan derivatives, and the material of Aquanova is chitosan, chitosan derivatives, and structural material.

IV. PERFORMANCE DATA

To verify that the SURECELL™ Gelling Fiber Wound Dressing is as safe and effective as predicate device, representative samples of SURECELL™ Gelling Fiber Wound Dressing were underwent a series of tests including bench testing (absorbency, gelling characteristics, pH, loss on drying, residue on ignition, heavy metals, bacterial endotoxins, breaking strength, packaging sealing, and sterility), biocompatibility testing (cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute toxicity, implantation) sterilization validation testing, and shelf life stability testing.

V. CONCLUSION

JIANGSU NEWVALUE Medical PRODUCTS CO., LTD. considers SURECELL™ Gelling Fiber Wound 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

SURECELL™ Gelling Fiber Wound Dressing and the predicate devices do not raise any questions of safety and effectiveness.