April 27, 2018

Virchow Biotech Pvt Ltd
Bruce Gibbins
Doctor
5903 SE Milwaukie Ave
Portland, Oregon 97202

Re: K172747
Trade/Device Name: Hyaluronic Acid Topical Wound Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 28, 2017
Received: September 12, 2017

Dear Bruce Gibbins:

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)*

Device Name

Hyaluronic Acid Topical Wound Cream 0.2%w/w

Indications for Use *(Describe)*

Hyaluronic Acid Topical Wound Cream 0.2%w/w is indicated for dressing and management of wounds such as partial to full thickness dermal ulcers (pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites), first and second degree burns.

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:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
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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)*

Device Name

Hyaluronic Acid Topical Wound Cream 0.2%w/w

Indications for Use *(Describe)*

Hyaluronic Acid Topical Wound Cream 0.2%w/w is indicated for dressing and management of minor burns, minor superficial cuts, minor lacerations, and minor abrasions; and minor irritation of the skin.

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.

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510(k) Summary

5.1 510(k) Summary for Prescription (Rx) of Hyaluronic Acid Topical Wound Cream 0.2%w/w:

5.1.1 510(k) Sponsor Information:

VIRCHOW BIOTECH PVT LTD
Plot No: 3l8 & 320,
3rd Floor, Swamy Ayyapa Co-Op Housing Society Ltd.
Madhapur, Hyderabad
Telangana State
India-500 081

5.1.2 Contact Person

Bruce Gibbins PhD,
5936 N Via Verdosa,
Tucson AZ 85750
Contact No: +1 503-781-7565
Email: blgibbins@gmail.com

Date: 13/03/2018

5.1.3 Device Information:

Trade Name (proprietary name)	**Common/Usual Name**	**Classification Name**	**Device Class**
Hyaluronic Acid Topical Wound Cream 0.2% w/w	Hyaluronic acid sodium salt hydrogel dressing	Dressing, Wound and Burn, Hydrogel	Unclassified

5.1.4 Legally marketed device to which substantial equivalence is being claimed:

Hyaluronic Acid Topical Wound Cream 0.2%w/w is substantially equivalent in function and intended use to the following commercially available unclassified, non-interactive wound and burn dressing:

Bionect® Cream (K963004) (FIDIA Pharmaceutical Corp.)

5.1.5 Description of the Device

Hyaluronic Acid Topical Wound Cream 0.2%w/w is a white or light straw colored hydrophilic viscous cream containing hyaluronic acid for topical use on wounds.

5.1.6 Explanation of how the device functions

The device, Hyaluronic Acid Topical Wound Cream 0.2%w/w is a hydrophilic topical cream that is intended for moisture management wound bed of acute and chronic dermal wounds. Hyaluronic Acid Topical Wound Cream 0.2%w/w functions as a moisture management cream to aid in providing a moist wound environment that is recognized to be conducive to healing.

5.1.7 The scientific concepts that form the basis for the device

Hyaluronic acid (HA) is a natural major component of the extracellular matrix and is important in providing support to the cellular constituents of tissues. HA is a muco-polysaccharide that has a high water binding capacity which enables it to trap and preserve water in the tissue environment. These properties serve to maintain tissues in a hydrated state which is needed for vitality and viability. The hydrophilic nature of HA is preserved when it is removed from the tissue environment. This enables HA to be used as a potent moisture management component of topical products such as Hyaluronic Acid Topical Wound cream 0.2%w/w. When used topically, the HA in Hyaluronic Acid Topical Wound Cream 0.2%w/w maintain moisture on the wound.

5.1.8 Physical and performance characteristics

Hyaluronic Acid Topical Wound Cream 0.2%w/w is topical cream base containing sodium hyaluronate 0.2%w/w. The Hyaluronic Acid Topical Wound Cream 0.2%w/w is a repeat use, preservative protected non-sterile topical product.

5.1.9 Indication of Use

Hyaluronic Acid Topical Wound Cream 0.2%w/w is indicated for dressing and management of wounds such as partial to full thickness dermal ulcers (pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites), first and second degree burns.

5.1.10 Summary of the technological characteristics and substantial equivalence

The characteristics of Hyaluronic Acid Topical Wound Cream 0.2%w/w are not different from the predicate device (Bionect® Cream). The proposed device uses the same technology and is intended for similar indications.

5.1.11 Assessment of Performance Data and Safety

As per regulatory requirements Biocompatibility testing for Hyaluronic Acid Topical Wound Cream 0.2%w/w was conducted according to ISO 10993 'Biological Evaluation of Medical Devices'. A series of comparative studies along with the predicate device, Bionect® cream, were performed to determine the safety of proposed device.

Conclusion:

The performed studies demonstrated that Hyaluronic Acid Topical Wound Cream 0.2%w/w is as safe and effective as the predicate device (Bionect® Cream) for its intended use on breached and compromised skin as a moist wound dressing.

510(k) Summary

5.2 510(k) Summary for Over-the-counter (OTC) of Hyaluronic Acid Topical Cream 0.2%w/w:

5.2.1 <u>510(k) Sponsor Information:</u>

VIRCHOW BIOTECH PVT LTD
Plot No: 3l8 & 320,
3rd Floor, Swamy Ayyapa Co-Op Housing Society Ltd.
Madhapur, Hyderabad
Telangana State
India-500 081

5.2.2 <u>Contact Person</u>

Bruce Gibbins PhD,
5936 N Via Verdosa
Tucson AZ 85750
Contact No: +1 503-781-7565
Email:blgibbins@gmail.com

Date: 13/03/2018

5.2.3 <u>Device Information:</u>

Trade Name (proprietary name)	**Common/Usual Name**	**Classification Name**	**Device Class**
Hyaluronic Acid Topical Wound Cream 0.2%w/w	Hyaluronic acid sodium salt hydrogel dressing	Dressing, Wound and Burn, Hydrogel	Unclassified

5.2.4 <u>Legally marketed device to which substantial equivalence is being claimed:</u>

Hyaluronic Acid Topical Wound Cream 0.2%w/w is substantially equivalent in function and intended use to the following commercially available unclassified, non-interactive wound and burn dressing:

Bionect® Cream (K963004) (FIDIA Pharmaceutical Corp.)

5.2.5 <u>Description of the Device</u>

Hyaluronic Acid Topical Wound Cream 0.2%w/w is a white or light straw colored hydrophilic viscous cream containing hyaluronic acid for topical use on wounds.

5.2.6 Explanation of how the device functions

The device, Hyaluronic Acid Topical Wound Cream 0.2%w/w is a hydrophilic topical cream that is intended for moisture management on wound bed of acute and chronic dermal wounds. Hyaluronic Acid Topical Wound Cream 0.2%w/w functions as a moisture management cream to aid in providing a moist wound environment that is recognized to be conducive to healing.

5.2.7 The scientific concepts that form the basis for the device

Hyaluronic acid (HA) is a natural major component of the extracellular matrix and is important in providing support to the cellular constituents of tissues. HA is a muco-polysaccharide that has a high water binding capacity which enables it to trap and preserve water in the tissue environment. These properties serve to maintain tissues in a hydrated state which is needed for vitality and viability. The hydrophilic nature of HA is preserved when it is removed from the tissue environment. This enables HA to be used as a potent moisture management component of topical products such as Hyaluronic Acid Topical Wound cream 0.2%w/w. When used topically, the HA in Hyaluronic Acid Topical Wound Cream0.2%w/w maintain moisture on the wound.

5.2.8 Physical and performance characteristics

Hyaluronic Acid Topical Wound Cream 0.2%w/w is topical cream base containing sodium hyaluronate 0.2%w/w. The Hyaluronic Acid Topical Wound Cream 0.2%w/w is a repeat use, non-sterile preservative protected topical product.

5.2.9 Indication of Use

Hyaluronic Acid Topical Wound Cream 0.2%w/w is indicated for dressing and management of minor burns, minor superficial cuts, minor lacerations, and minor abrasions; and minor irritation of the skin.

5.2.10 Summary of the technological characteristics and Substantial equivalence

The characteristics of Hyaluronic Acid Topical Wound Cream 0.2%w/w are not different from the predicate device (Bionect® Cream). The proposed device uses the same technology and is intended for similar indications.

5.2.11 Assessment of Performance Data and Safety

As per regulatory requirements Biocompatibility testing for Hyaluronic Acid Topical Wound Cream 0.2%w/w was conducted according to ISO 10993 'Biological Evaluation of Medical Devices'. A series of comparative studies along with the predicate device, Bionect® Cream, were performed to determine the safety of proposed device.

Conclusion:

The performed studies demonstrated that Hyaluronic Acid Topical Wound Cream 0.2%w/w is as safe and effective as the predicate device (Bionect® Cream) for its intended use on breached and compromised skin as a moist wound dressing.