DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 22, 2016

Virchow Biotech PVT LTD
Mr. Bruce Gibbons
Project Head
5903 SE Milwaukie Avenue
Portland, OR 97202

Re: K153565
Trade/Device Name: DONASORB Silver Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 13, 2016
Received: August 22, 2016

Dear Mr. Gibbons:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153565

Device Name

DONASORB™

Indications for Use *(Describe)*

OTC: DONASORB™ is intended for use in management of minor cuts, minor abrasions, minor lacerations and minor 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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153565

Device Name

DONASORB™

Indications for Use *(Describe)*

Rx: DONASORB™ is intended for use by prescription for the management of partial and full thickness wounds such as pressure ulcers, vascular ulcers, diabetic wounds, lacerations, abrasions, surgical wounds, graft sites, skin tears, and first and second degree burns.

DONASORB™ is not indicated for use on third 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)

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5.2 510(k) Summary for OTC:

5.2.1 Submitter's Details

Name of the 510(k) sponsor:	**VIRCHOW BIOTECH PVT LTD**
Address:	Plot No: 318 & 320, 3rd Floor, Swamy Ayyapa Co-Op Housing Society Ltd, Madhapur, Hyderabad, Telangana, India-500 081.
Contact Person:	BRUCE GIBBINS PhD, 5903 SE Milwaukie Avenue, Portland OR 97202. Contact No: 503-781-7565 Email: blgibbins@gmail.com

5.2.2 Device Name

Proprietary name of device:	**DONASORB™**
Generic Name/Common Name	Silver Wound Dressing
Classification Name:	Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code:	FRO
Regulatory Class:	Unclassified

5.2.3 Legally Marketed Predicate Devices:

AcryDerm Silver Antimicrobial Barrier Wound Dressing **(K991818).**

5.2.4 Device Description

DONASORB™ is a moist hydrogel sheet containing the antimicrobial ionic silver in the form of silver chloride which is intended to be a primary wound contact dressing to manage wound moisture. The base matrix of the subject device is composed of cross-linked polyacrylate sheet incorporating antimicrobial ionic silver in a silver chloride reservoir. Ionic silver in the form of silver chloride in the sheet inhibits the growth of broad spectrum microbes on or within the dressing.

The Device is a sterile single use dressing supplied on PVC (Poly Vinyl Chloride) transparent carrier sheet, packed in a medical grade heat sealed aluminum foil pouch. Five single piece pouches are packed in a Mono-carton along with a package insert. Barrier and Antimicrobial Effectiveness was demonstrated to last for up to 2 days per bench testing. It is recommend to use DONASORB™ for up to 2 days or should be removed gently when completely saturated with wound fluids; whichever occurs first. It is available in sterile sheets of 2x2 cm, 2x4 cm, 4x4 cm, 4x8 cm, 8x8 cm and 10x10 cm sizes.

5.2.5 Mechanism of Action

Primary function of the DONASORB™ device is to manage wound exudates. The antimicrobial action of the dressing is intended to inhibit or kill microbes to prevent them from colonizing the dressing and entering the wound. The device acts a barrier between the wound and the surrounding environment.

5.2.6 Statement of Intended Use

DONASORB™ is a hydrophilic dressing that aids in the management of wound exudate. The device contains ionic silver in the form of silver chloride minimize the bacterial growth on or within the dressing. These characteristics constitute the device as an effective barrier to bacterial penetration.

5.2.7 Indications for Use:

OTC: DONASORB™ is intended for use in management of minor cuts, minor abrasions, minor lacerations and minor burns.

5.2.8 Device Technological Characteristics and Substantial Equivalence

DONASORB™ is an antimicrobial barrier dressing containing silver chloride substantially equivalent to AcryDerm Silver Antimicrobial Wound Dressing (hereafter referred as AcryDerm); cleared under 510k number **K991818** by AcryMed Inc.

DONASORB™ is a sterile, single use cross-linked polyacrylate hydrogel sheet containing ionic silver in a silver chloride reservoir similar to its predicate device AcryDerm. The subject device is substantially equivalent to predicate device in its

composition, indication for use and functionality, and does not raise any additional risks in terms of safety and performance. The inactive ingredients of the device may be similar to the predicate.

5.2.9 Assessment of Performance Data and Safety

Both the Device (DONASORB™) and Predicate (AcryDerm Silver Antimicrobial Barrier Wound Dressing) are composed of cross-linked polyacrylate sheet with the incorporation of antimicrobial ionic silver in a silver chloride reservoir. DONASORB™ was evaluated for its effective barrier property (Bacterial barrier property testing) in the prevention of bacterial penetration through the dressing and the antimicrobial efficiency (Antimicrobial efficacy test) of the device to inhibit the growth of microorganisms. The tests that were performed simulates the clinical conditions of use, using 3 Gram positive, 3 Gram negative and 2 fungi organisms. At time points more than 24 hours, dressing was challenged with repeated inoculation.

Barrier and Antimicrobial Effectiveness was demonstrated to last for up to 2 days per bench testing. Based on the test results, it is recommend to use DONASORB™ for up to 2 days or should be removed gently when completely saturated with wound fluids; whichever occurs first.

As per the regulatory requirement, safety of DONASORB™ has been evaluated in accordance with **ISO 10993**. The study design included comparative testing of DONASORB™ with predicate device AcryDerm for ***In Vitro*** **Cytotoxicity Study, Acute Toxicity Test, Intracutaneous Irritation/Reactivity Study, Skin Sensitization testing, and Sub chronic toxicity test.** The studies have demonstrated DONASORB™ to be substantially similar to its predicate.

Sterilization: DONASORB™ will be provided as a sterile single use device.

5.2.10 Manufacturing

DONASORB™ will be manufactured according to the product specification under the good manufacturing practices that ensures the device is safe and effective for its intended use.

5.1 510(k) Summary for Rx:

5.1.1 Submitter's Details

Name of the 510(k) sponsor:	**VIRCHOW BIOTECH PVT LTD**
Address:	Plot No: 318 & 320, 3rd Floor, Swamy Ayyapa Co-Op Housing Society Ltd, Madhapur, Hyderabad, Telangana, India-500 081.
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Proprietary name of device:	**DONASORB™**
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Regulatory Class:	Unclassified

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AcryDerm Silver Antimicrobial Barrier Wound Dressing **(K991818).**

5.1.4 Device Description

DONASORB™ is a moist hydrogel sheet containing the antimicrobial ionic silver in the form of silver chloride which is intended to be a primary wound contact dressing to manage wound moisture. The base matrix of the subject device is composed of cross-linked polyacrylate sheet incorporating antimicrobial ionic silver in a silver chloride reservoir. Ionic silver in the form of silver chloride in the sheet inhibits the growth of broad spectrum microbes on or within the dressing.

The Device is a sterile single use dressing supplied on PVC (Poly Vinyl Chloride) transparent carrier sheet, packed in a medical grade heat sealed aluminum foil pouch. Five single piece pouches are packed in a Mono-carton along with a package insert.

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