HemCon Medical Technologies, Inc.
Máire Ní Beilliú, Ph.D.
VP Regulatory & Quality
720 SW Washington Street, Suite 200
Portland, Oregon 97205

April 21, 2023

Re: K153582
Trade/Device Name: Prometheus ChitoGauze XR PRO
Regulatory Class: Unclassified
Product Code: QSY

Dear Máire Ní Beilliú, Ph.D.:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 25, 2016. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

May 25, 2016

HemCon Medical Technologies, Inc.
Máire Ní Beilliú, PhD
VP Regulatory & Quality
720 SW Washington Street, Suite 200
Portland, Oregon 97205

Re: K153582
Trade/Device Name: Prometheus ChitoGauze XR Pro
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 26, 2016
Received: April 28, 2016

Dear Dr. Ní Beilliú:

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" (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.

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,

Jennifer R. Stevenson -A

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)*
K153582

Device Name
Prometheus ChitoGauze® XR PRO

Indications for Use *(Describe)*
Prometheus ChitoGauze® XR PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds

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."

720 SW Washington Street, Suite 200 Portland, OR 97205-3504 USA

TEL: +1.503.245.0459 **FAX:** +1.503.245.1326 **WEB:** www.hemcon.com

510(k) Summary

I. Submitter:

Company Name:	HemCon Medical Technologies, Inc.
Company Address:	720 SW Washington Street, Suite 200 Portland, OR 97205-3504
Contact Person:	Máire Ní Beilliú PhD VP Regulatory & Quality
Contact Phone:	(971) 327.5729
Contact Fax:	(503) 245.1326
Date of Preparation:	23rd May 2016

II. Device

Trade Name:	**Prometheus ChitoGauze® XR PRO**
Common Name:	Chitosan Wound Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulatory Class:	Unclassified
Classification Panel:	878 – General and Plastic Surgery

III. Predicate Device(s):

Predicate Device:	HemCon® ChitoGauze® (**K090026**, **K092357**) / ChitoGauze® XR (**K102546**)
Reference Device:	HemCon GuardaCare™XR (**K103641**)

The predicate device has not been subject to a design related recall.

IV. Description of the Device:

Prometheus ChitoGauze® XR PRO is composed of standard polyester/rayon blend non-woven medical gauze with a radiopaque filament that is coated with chitosan. The dressing is z-folded to the appropriate size and vacuum sealed in a pre-printed foil pouch. The pouched dressing is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10^{-6}.

The hemostatic properties of chitosan enhance the ability of the medical gauze to control bleeding. The radiopaque filament allows for easy detection via X-ray to prevent the dressing from being inadvertently left on the wound.

720 SW Washington Street, Suite 200 Portland, OR 97205-3504 USA

TEL: +1.503.245.0459 **FAX:** +1.503.245.1326 **WEB:** www.hemcon.com

V. Indications for Use:

The Indications for Use statement for Prometheus ChitoGauze® XR PRO is identical to the predicate device, ChitoGauze® XR PRO (K102546).

Prometheus ChitoGauze® XR PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds

VI. Comparison of Technological Characteristics with the Predicate Device:

The subject device is technologically equivalent to the currently marketed ChitoGauze® XR product.

VII. Performance Data:

Performance testing which has been performed on the device includes:

- Biocompatibility testing per ISO 10993
- *in vivo* efficacy testing
- Radiopacity testing

Sterility

A sterility validation was completed following ISO 11137 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Biocompatibility Testing

Biocompatibility testing has been conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", May 1st 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" as recognized by FDA.

ChitoGauze® XR PRO is a surface-contacting device, in contact with breached or compromised surfaces which may be used for prolonged exposure (≥ 24 hrs ≤ 30 days). Cytotoxicity, irritation, sensitization and acute systemic toxicity testing has been performed by contract testing laboratories under GLP conditions per standard protocols.

in vivo Efficacy – Hemostatic Properties

Two separate in vivo studies were designed and conducted to establish the hemostatic efficacy of the product in different injury types created to represent the likely use of the different product sizes. In both studies the device was tested side-by-side against a competitive hemostatic dressing. The first study tested the ability of the 4 inch by 4 yard size to control bleeding in 6mm femoral perforation injury in a swine. The second study measured the ability of a two inch by two inch 8-ply size to control bleeding in a splenic capsular strip injury in a swine. In both cases, the device proved to successfully control bleeding at least as well as the competitive product used as a reference.

720 SW Washington Street, Suite 200 Portland, OR 97205-3504 USA

TEL: +1.503.245.0459 **FAX:** +1.503.245.1326 **WEB:** www.hemcon.com

Radiopacity:

The radiopacity of ChitoGauze® XR PRO was determined via testing performed in accordance with ASTM F640-07 Method C (Standard Test methods for Determining the Radiopacity for Medical Use). The product was found to be equivalent to the radiopacity of the ASTM Radiopacity Standard (101x76x0.9 mm 99+% 1100 alloy aluminum sheet) and was therefore determined to be acceptable.

Clinical Performance Data:

No clinical data was required for evaluation of this device.

Summary:

The conclusion drawn from the technological characteristics and non-clinical performance data is that Prometheus ChitoGauze® XR PRO has been found to have a safety and efficacy profile that is substantially equivalent to the predicate device ChitoGauze® XR PRO which is marketed for the same intended use.