HemCon Medical Technologies, Inc.
c/o Kevin Hawkins
Director - Quality and Regulatory
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223-4363

July 28, 2023

Re: K090026
Trade/Device Name: ChitoGauze™
Regulatory Class: Unclassified
Product Code: QSY

Dear Kevin Hawkins:

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 March 31, 2009. 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
9200 Corporate Boulevard
Rockville MD 20850

HemCon Medical Technologies, Inc.
% Mr. Kevin Hawkins
Director, Quality and Regulatory
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223

MAR 31 2009

Re: K090026
Trade/Device Name: ChitoGauze™
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 30, 2008
Received: January 5, 2009

Dear Mr. Hawkins:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090026

Device Name: ChitoGauze™

Indications For Use:

Indications for Use (Rx):
ChitoGauze is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

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

Prescription Use ___X__ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraus for MXM 3/13/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090026

HemCon MEDICAL TECHNOLOGIES INC

510(k) Summary

MAR 31 2009

Trade Name:	ChitoGauze™
Common Name:	Wound Dressing
Classification Name:	Dressing
Product Code:	FRO
Predicate Device(s):	HemCon® Bandage (K072486) QuikClot® eX™ (K072474)
Company Name:	HemCon Medical Technologies, Inc.
Company Address:	10575 SW Cascade Avenue, Suite 130 Portland, OR 97223
Contact Person:	Kevin Hawkins Director – Quality & Regulatory
Contact Phone:	(503)245.0459 x114
Contact Fax:	(503)245.1326
Date of Preparation:	20 March 2009

Description of the Device:

The ChitoGauze dressing is composed of standard polyester/rayon blend non-woven medical gauze that is coated with chitosan. The four inch by four yard (4" x 4 yds) dressing is z-folded and packaged in a peelable 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.

Intended Use:

ChitoGauze™ is intended to be a hemostatic wound dressing.

Indications for Use (Rx):
ChitoGauze is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

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

Technological Characteristics:

ChitoGauze is technologically similar to at least two predicate devices. The HemCon Bandage has demonstrated the safety and efficacy of a chitosan based hemostatic dressing. QuikClot® eX™has demonstrated the safety and efficacy of a standard, non-woven medical gauze coated with a hemostatic material. ChitoGauze combines the

chitosan material of one predicate with the coated gauze of the other and is therefore technologically similar to both.

Non-Clinical Performance Data:

Biocompatibility
Biocompatibility has been demonstrated per ISO 10993.

In Vivo Efficacy
In vivo testing evaluated the efficacy of ChitoGauze versus lap sponges, uncoated gauze and coated gauze (competitive) in an extreme trauma model. ChitoGauze exhibited substantially equivalent efficacy.

Reduction of Microorganisms:
ChitoGauze™ was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the level of antibacterial effectiveness. The clinical utility of these results is unknown.

Microorganism	Gram Stain	Log Reduction
Staphylococcus aureus (MRSA) ATCC 33591	+	>4.1
Staphylococcus aureus (MRSA) ATCC BAA-1556	+	>4.2
Staphylococcus epidermidis ATCC 12228	+	>4.2
Pseudomonas aeruginosa ATCC 9027	-	>4.1
Enterococcus faecalis (VRE) ATCC 51299	+	>4.0
Acinetobacter baumanii ATCC 15308	-	>4.4
Citrobacter freundii ATCC 8090	-	>4.3
Enterobacter cloacae ATCC 13047	-	>4.1
Streptococcus mutans ATCC 25175	+	>4.0
Streptococcus pneumoniae ATCC 10015	+	>5.1
Escherichia coli ATCC 8739	-	>4.1
Klebsiella pneumoniae ATCC 4352	-	>4.0
Streptococcus pyogenes ATCC 19615	+	>4.2
Salmonella choleraesius ATCC 10708	-	>4.1
Stenotrophomonas maltophilia ATCC 12714	-	>4.0
Citrobacter koseri ATCC 25408	-	>4.1
Proteus mirabilis ATCC 4630	-	>4.2
Proteus vulgaris ATCC 12454	-	>4.3
Moraxella catarrhalis ATCC 8193	-	>4.1
Clostridium difficile ATCC 9689	+	>4.0
Shigella species ATCC 11126	-	>4.0
Micrococcus luteus ATCC 49732	+	>4.0
Vibrio cholerae ATCC 11558	-	>4.1
Enterobacter aerogenes ATCC 13048	-	4.8
Enterococcus faecalis (VRE) ATCC 700802	+	2.6
Serratia marcescens ATCC 13880	-	5.0

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Sterility
A sterility validation for ChitoGauze was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Clinical Performance Data:

No clinical data was required for evaluation of this device.

Substantial Equivalence:

The conclusion drawn from the technological characteristics and non-clinical performance data is that the device is as safe and effective as the predicate devices.