HemCon 510(k) Notification

2. SECTION 5 - 510(K) SUMMARY

MAY 15 2008

Name and Address of Sponsor:

HemCon Medical Technologies, Inc.
10575 SW Cascade Avenue, Suite 103
Portland, OR 97223

Device Name:

Proprietary Name: Hemcon Bandage; HemCon Bandage OTC; ChitoFlex-Surgical

Common Name: Wound Dressing
Classification Name: Dressing
Product Code: FRO

Establishment Registration Number:

9053189

General Description:

The HemCon Bandage and HemCon Bandage OTC were cleared in K043050 on June 3, 2005. Additionally, the Hemcon ChitoFlex-Surgical dressing was cleared in K071519 on August 6, 2007 for temporary surgical use. With this 510(k), the bandage remains unchanged; this application solely expands the indications for use.

The HemCon dressings are a hemostatic chitosan dressing for the external temporary control of severely bleeding wounds intended for emergency use. In addition, the dressing also controls bleeding in patients following hemodialysis.

In vivo testing evaluated the efficacy of the Hemcon Bandage versus control to provide hemostasis in femoral artery catheter puncture sites. This data supports the effectiveness of the Hemcon Bandage in achieving hemostasis at percutaneous catheter sites. In addition, the Hemcon dressings are substantially equivalent to other legally marketed chitosan-based bandages with the same indications. With this 510(k) Hemcon is proposing to add the following indications to the Hemcon Bandage and ChitoFlex-Surgical dressing:

"The dressing is also indicated for the control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites."

The predicate devices are indicated for use in control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites. The HemCon Bandage is substantially equivalent to these predicate devices in that it has similar intended use and indications as well as the majority are chitosan-based dressings. The predicated devices include: HemCon Bandage (K043050, cleared June 3, 2005), HemCon ChitoFlex-Surgical (K071519, cleared August 6, 2007) Hemostasis, LLC Corporation's ExcelArrest (K072900, cleared Oct. 26, 2007), Perclose/Abbott Labs' Chito-Seal (K021062, cleared Aug 23, 2002), Scion Cardio-Vascular, Inc's (Medtronic) Clo-Sur (plus) P.A.D. (K032986, cleared Mar 1, 2004) and Medafor, Inc.'s Hemaderm containging MPH (Microporous Polysaccharide Hemospheres) (K033666, cleared Dec. 17, 2003).

Indications for Use:

Indication Rx Hemcon Bandage: The HemCon Bandage is a hemostatic dressing for the external temporary control of severely bleeding wounds intended for emergency use. In addition, the HemCon Bandage also controls bleeding in patients following hemodialysis.

The dressing is also indicated for the control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Indications Rx ChitoFlex-Surgical:

HemCon ChitoFlex™-Surgical is intended for use as a dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatalogical, etc.) and traumatic injuries.

The dressing is also indicated for the control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Contact Person(s) and Phone Number:

Kevin Hawkins
Director – Quality & Regulatory
Phone (503)245.0459 x114 Fax (503)245.1326

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

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

Re: K080818
Trade/Device Name: HemCon Bandage
ChitoFlex-Surgical
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 28, 2008
Received: May 2, 2008

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,

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

Enclosure

Applicant: HemCon Medical Technologies, Inc.
510(k) Number (if known): ~~Not Yet Assigned~~ K080818
Device Name: ChitoFlex-Surgical

Indications for Use:

HemCon ChitoFlex™-Surgical is intended for use as a dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatalogical, etc.) and traumatic injuries.

The dressing is also indicated for the control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Prescription Use ☒ AND/OR **Over-The-Counter Use** ☐
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for man

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

510(k) Number K080818

1. SECTION 4- INDICATIONS FOR USE STATEMENT

Applicant: HemCon Medical Technologies, Inc.
510(k) Number (if known): ~~Not Yet Assigned~~ K080818
Device Name: HemCon Bandage

Indications for Use:

The HemCon Bandage is a hemostatic dressing for the external temporary control of severely bleeding wounds intended for emergency use. In addition, the HemCon Bandage also controls bleeding in patients following hemodialysis.

The dressing is also indicated for the control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** ☐ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Ogle for mgm

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

510(k) Number K080818