510(K) Summary

AUG - 6 2008

HemCon® Bandage
510(k) K072486

Name and Address of Sponsor:

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

Device Name:

Proprietary Names:
HemCon® Bandage;
ChitoFlex Hemostatic Dressing;
HemCon® Bandage OTC
Common Name: Wound Dressing
Classification Name: Dressing
Product Code: FRO

Establishment Registration Number:

3004050854

Contact Person and Phone Number:

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

Device Description:

The HemCon® Bandage is manufactured from chitosan. When applied directly to the wound, the HemCon® Bandage controls bleeding. The HemCon® Bandage is a sterile chitosan based dressing intended for use 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 HemCon® Bandage OTC is indicated for the local management of bleeding such as laceration and minor bleeding.

The original HemCon® Bandage and HemCon® Bandage OTC were cleared via 510(k) K043050 on 03 June 2005 to include the description that the bandage provides an antibacterial barrier as demonstrated by AATCC Test Method 100-2004, Evaluation of Antibacterial Finishes (Technical Manual of the America Association of Textile Chemists and Colorists) in laboratory testing for two micro-organisms. This submission expands this antibacterial claim to a total of twenty-four micro-organisms.

The HemCon® Bandage is similar to the original HemCon® Bandage and another antibacterial wound dressing, Maersk Medical's Arglaes-AB Antimicrobial (K990810, cleared 17 September 1999), the HemCon® Bandage was challenged with microbial strains *in vitro* to support the claim of antibacterial barrier activity and extend the list of microorganisms used in the challenge test.

Indication for Use Rx:

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.

Indications for Use OTC:

The HemCon® Bandage OTC is indicated for the local management of bleeding such as laceration and minor bleeding.

Technical Characteristics:

The HemCon® Bandage demonstrated through *in vitro* laboratory testing log 4 reductions of multiple organisms. Additionally, testing was conducted demonstrating the bandage is a barrier to microbial penetration against log 6 inoculum. Only single strains of most species mentioned have been studied. Testing challenged for log reduction and barrier abilities against the following microbial strains:

Staphylococcus aureus (MRSA) ATCC 33591
Klebsiella pneumoniae ATCC 4352
Escherichia coli ATCC 8739
Streptococcus pyogenes ATCC 19615
Staphylococcus epidermidis ATCC 12228
Salmonella choleraesuis ATCC 10708
Pseudomonas aeruginosa ATCC 9027
Acinetobacter baumanii ATCC 15308
Enterococcus faecalis (VRE) ATCC 51299
Enterococcus faecalis ATCC 700802
Serratia marcescens ATCC 13880
Stenotrophomonas maltophilia ATCC 12714
Streptococcus mutans ATCC 25175
Streptococcus pneumoniae ATCC 10015
Shigella species ATCC 11126
Enterobacter aerogenes ATCC 13048
Proteus mirabilis ATCC 4630
Proteus vulgaris ATCC 12454
Citrobacter freundii ATCC 8090
Enterobacter cloacae ATCC 13047
Micrococcus luteus ATCC 49732
Vibrio cholerae ATCC 11558
Moraxella catarrhalis ATCC 8193
Clostridium difficile ATCC 9689

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

Hemcon Medical Technologies, Inc.
% Mr. Kevin Hawkins
Director, Quality & Regulatory
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97233

Re: K072486
Trade/Device Name: HemCon® Bandagesh, HemCon® Bandage OTC
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 14, 2008
Received: July 15, 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

K072486

1. INDICATIONS FOR USE STATEMENT

Applicant: HemCon, Inc.
510(k) Number (if known): Not Yet Assigned
Device Name: HemCon® Bandage

Indications for Use:

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.

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 N Milhoan

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

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(Posted November 13, 2003)

K072486

Indications for Use Statement

Applicant: HemCon, Inc.
510(k) Number (if known): Not Yet Assigned
Device Name: HemCon® Bandage OTC

Indications for Use:

The HemCon® Bandage OTC is indicated for the local management of bleeding such as laceration and minor bleeding.

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)

Mark N Milhous

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

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