HemCon® Dental Dressing 510(k) Notification

JUL - 7 2006

5. SECTION 5 - 510(K) SUMMARY

Name and Address of Sponsor:

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

Device Name:

Proprietary Name: Hemcon® Dental Dressing

Common Name: Oral Wound Dressing
Classification Name: Dressing
Product Code: Unclassified

Establishment Registration Number:

9053189

General Description:

The HemCon® Dental Dressing is identical in material, design and composition to the legally marketed HemCon® Bandage (K023298, cleared 04 November 2002 with update K043050, cleared 03 June 2005). The only differences are the indication for use in the oral cavity and the reduction in size for the use in the oral cavity (10 cm x 10 cm for the legally marketed HemCon® bandage versus 10 mm x 12 mm for the dental dressing). Additionally, the HemCon® Dental Dressing is provided without the non-stick backing used on the HemCon® Bandage.

The HemCon® Dental Dressing is a lyophilized (freeze-dried) chitosan-based dressing designed to optimize the mucoadhesive surface density and structural integrity of chitosan at the wound site. The HemCon® Dental Dressing may be manufactured to any size and is currently available in 10 mm x 12 mm rectangular dressing and is packaged in a vacuum-sealed aluminum pouch and processed with gamma radiation for sterile single-use only application.

Indication for Use:
The HemCon® Dental Dressing is an oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief.

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

JUL - 7 2006

Mr. Kevin Hawkins
Director-Quality & Regulatory
HemCon, Incorporated
10575 SW Cascade Boulevard, Suite 103
Portland, Oregon 97223

Re: K060363
Trade/Device Name: HemCon® Dental Bandage
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MGQ
Dated: June 14, 2006
Received: June 15, 2006

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.

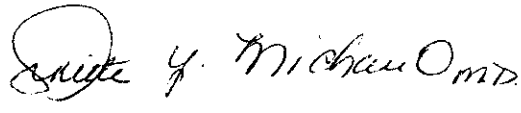
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. SECTION 4- INDICATIONS FOR USE STATEMENT

Applicant: HemCon, Inc.
510(k) Number (if known): K060363
Device Name: HemCon® Dental Bandage

Indications for Use:

The HemCon® Dental Dressing is an oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief.

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

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...(k) Number: K060363

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(Posted November 13, 2003)