HemCon, Inc.
James F. Hensel
President
10575 SW Cascade Avenue, Suite 130
Tigard, Oregon 97223

June 11, 2023

Re: K030946
Trade/Device Name: HemCon™ Bandage OTC
Regulatory Class: Unclassified
Product Code: QSY

Dear James F. Hensel:

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 June 19, 2003. 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

JUN 19 2003

Mr. James F. Hensel
President
HemCon, Inc.
10575 SW Cascade Avenue, Suite 130
Tigard, Oregon 97223

Re: K030946
Trade/Device Name: The HemCon™ Bandage OTC
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 25, 2003
Received: March 26, 2003

Dear Mr. Hensel:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030946

SECTION T - STATEMENT OF INDICATIONS FOR USE

INDICATIONS FOR USE

Applicant: HemCon, Inc.

510(K) Number (If known): Not Yet Assigned

Device Name: The HemCon™ Bandage OTC

The HemCon™ Bandage OTC is intended to be available Over the Counter for the following indication

Indications for Use:

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

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

_____ _____ _____ _____

_____Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K030946

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

SECTION P - 510(K) SUMMARY

JUN 19 2003

Trade Name:	HemCon™ Bandage OTC
Device Class:	Class 1
Classification Panel:	878 - General and Plastic Surgery
Common Name:	Traumatic Wound Dressing
Classification Name:	Bandage, Liquid
Predicate Devices:	HemCon™ Bandage, HemCon, Inc
	510(K) # K023298 (by reference)
	ProDeln™ Patch/ SyvekPatch®, Marine Polymer Technologies
	510(k) # K984177
Submitted by:	James F. Hensel, President
Company Name:	HemCon, Inc.
Company Address:	10575 SW Cascade Ave., Suite 130
	Tigard, OR 97223
Company Telephone:	503-245-0459
Company Fax:	503-245-1326
Prepared On:	March 25, 2003

The HemCon™ Bandage OTC is intended for the local management of bleeding such as laceration and minor bleeding. The HemCon™ Bandage OTC is manufactured from chitosan, a material consisting of cellulosic polymer, poly-*N*-acetylglucosamine. The HemCon™ Bandage OTC device is packaged in a foil package and are provided sterile. Performance data for the HemCon™ Bandage OTC has been previously submitted in the referenced device submission.

The HemCon™ Bandage OTC is similar to Marine Polymer Technologies' ProDeln™ Patch in intended use, indications, material, performance, sterilization method, and method of application. In summary, the HemCon™ Bandage OTC is expected to achieve the same safety and effectiveness as the predicate devices mentioned above. Predicate device comparison tables are included in this submission.