HemCon, Inc.
John W. Morgan
President and CEO
10575 SW Cascade Avenue, Suite 130
Tigard, Oregon 97223-4363

June 11, 2023

Re: K043050
Trade/Device Name: HemCon® Bandage and HemCon® Bandage OTC
Regulatory Class: Unclassified
Product Code: QSY

Dear John W. Morgan:

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 13, 2005. 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 13 2005

Mr. John W. Morgan
President and CEO
HemCon Incorporated
10575 SW Cascade Avenue, Suite 130
Tigard, Oregon 97223-4363

Re: K043050
Trade/Device Name: HemCon® Bandage and HemCon® Bandage OTC
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 8, 2005
Received: April 11, 2005

Dear Mr. Morgan:

This letter corrects our June 3,2005 substantially equivalent letter.

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.

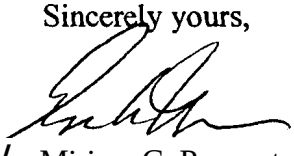
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



%– Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE
Applicant: HemCon, Inc.
510(K) Number (if known): K043050
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)

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

510(k) Number K043050

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

INDICATIONS FOR USE
Applicant: HemCon, Inc.
510(K) Number (if known): K043050
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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K043050

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

JUN 3 - 2005

510(k) SUMMARY K043050

page 1 of 2

Trade Name:	HemCon® Bandage HemCon® Bandage OTC
Device Class:	Class 1
Classification Panel:	878 - General and Plastic Surgery
Common Name:	Traumatic Wound Dressing
Classification Name:	Dressing
Predicate Devices:	HemCon® Bandage 510(k) # K023298 HemCon® Bandage OTC 510(k) # K030946
Submitted by:	John W. Morgan, President & CEO
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:	01 October 2004 (Updated 11 May 2005)

The HemCon® Bandage is intended as an external temporary wound treatment for the control of severely bleeding wounds for emergency use. In addition, the HemCon® Bandage also controls bleeding in patients following hemodialysis. The HemCon® Bandage OTC is intended for the local management of bleeding such as laceration and minor bleeding. Performance data for the HemCon® Bandage and the HemCon® Bandage OTC have been previously submitted in the referenced predicate device submissions. The HemCon® Bandage and the HemCon® Bandage OTC are antibacterial barriers as demonstrated by AATCC Test Method 100-2004, Evaluation of Antibacterial Finishes (Technical Manual of the American Association of Textile Chemist and Colorists) in laboratory testing with *Staphylococcus aureus* and *Klebsiella pneumonia*.

The HemCon® Bandage and the HemCon® Bandage OTC are each applied to the wound and held in place until it adheres to the wound and hemostasis is

achieved. Then, an outer bandage is applied to secure the dressing on the wound site.

The HemCon® Bandage and the HemCon® Bandage OTC are manufactured from chitosan, a material consisting of cellulosic polymer, poly[β(1→4)-2-amino-2-deoxy-D-glucopyranose]. Several biomedical applications of chitosan have already been reported. Chitosan has many advantages due to its absence of toxicity and biodegradability without damaging the environment. It is a biocompatible material that breaks down slowly into a harmless product, glucosamine, which is absorbed completely by the body. Complete biocompatibility data is presented in the referenced predicate devices submissions.

These devices are packaged in a foil package and provided sterile. They are sterilized by gamma irradiation at a dose adequate to ensure a SAL of 10^{-6}. The validation study conducted according to ISO 11137, Method IIB is on file at HemCon.

The HemCon® Bandage and HemCon Bandage OTC are identical to the HemCon® Bandage and HemCon® Bandage OTC in intended use, material, performance, sterilization method, and method of application and are expected to achieve the same safety and effectiveness as the predicate devices mentioned above while providing additional antibacterial barrier properties.