



Food and Drug Administration
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November 10, 2015

HemCon Medical Technologies Incorporated
Ms. Jody Oyama
Vice President Clinical and Regulatory Market Strategy United States
720 Southwest Washington Street, Suite 200
Portland, Oregon 97205

Re: K150916

Trade/Device Name: HemCon Bandage PRO, HemCon Patch PRO, HemCon Strip PRO,
HemCon Strip First Aid PRO, ChitoFlex PRO

Regulatory Class: Unclassified

Product Code: FRO

Dated: October 12, 2015

Received: October 14, 2015

Dear Ms. Oyama:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150916

Device Name
HemCon Bandage PRO (OTC)

Indications for Use (Describe)

The HemCon Bandage OTC is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions and in patients on anticoagulation therapy. The HemCon Bandage OTC also provides an antibacterial barrier against a wide range of gram positive and gram negative organisms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

510(k) Number (if known)
K150916

Device Name
HemCon Bandage PRO

Indications for Use (Describe)

The HemCon Bandage PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K150916

Device Name
HemCon ChitoFlex PRO

Indications for Use (Describe)

HemCon ChitoFlex PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K150916

Device Name
HemCon Patch PRO

Indications for Use (Describe)

The HemCon Patch PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K150916

Device Name
HemCon Strip First Aid PRO

Indications for Use (Describe)

The HemCon Strip First Aid PRO is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions and in patients on anticoagulation therapy. The HemCon Strip First Aid PRO also provides an antibacterial barrier against a wide range of gram positive and gram negative organisms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K150916

Device Name

HemCon Strip PRO

Indications for Use (Describe)

The HemCon Strip PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary - K150916

HemCon 510(k) Notification

I. Submitter:

Company Name: HemCon Medical Technologies, Inc.
Company Address: 720 SW Washington Street, Suite 200
Portland, OR 97205-3504

Contact Person: Máire Ní Beilliú PhD
VP Regulatory & Quality
Contact Phone: (971) 327.5729
Contact Fax: (503) 245.1326

Date of Preparation: 6th November 2015

II. Device

Trade Name: HemCon® Bandage PRO, HemCon® Bandage PRO OTC, HemCon® Patch PRO, HemCon® Strip PRO, HemCon® Strip First Aid PRO, HemCon® ChitoFlex PRO

Common Name: Wound Dressing
Classification Name: Dressing
Product Code: FRO
Regulatory Class: Unclassified

III. Predicate Device(s):

Predicate Devices: HemCon Bandage (K080818, K072486, K071519, K043050, K030946, K023298)
Clo-Sur Pad (Plus) P.A.D. Scion Cardio-Vascular, Inc (K112961, K092552, K032986)

The predicate devices have not been subject to a design related recall.

IV. Description of the Device:

The HemCon® Bandage family of products are lyophilized (freeze dried) chitosan based dressings designed to optimize the muco adhesive surface density and structural integrity of chitosan at the site of injury. The bandages are soft, pliable, off-white, non-woven, lamellar dressings composed of a non-mammalian biocompatible, hydrophilic cellulose polymer, poly-N-acetylglucosamine (NAG), isolated from arctic shrimp “Pandalus Borealis’ chitosan.

When applied directly to a wound the dressing controls bleeding. The chitosan dressings offer an antibacterial barrier against a wide range of gram positive and gram negative organisms including antibiotic resistant *Staphylococcus aureus* (MRSA), *Enterococcus faecalis* (VRE) and *Acinetobacter baumannii*. Only single strains of most species mentioned have been studied.

The HemCon Bandage Family of products may be manufactured to any size and are currently available in sizes: 1.5” x 1.5”, 1” x 3”, 1” x 4”, 2” x 2”, 2”x 4”, 4”x 4”,3” x 9” and 3” x 28”.

The HemCon Bandage family products are safe, durable, highly effective, and do not contain human proteins or clotting factors.

V. Indications for Use:

Prescription Use:

HemCon® Bandage PRO:

The HemCon® Bandage PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins

HemCon Patch® PRO:

The HemCon® Patch PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins

HemCon® Strip PRO:

The HemCon® Strip PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds:

lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins

HemCon® ChitoFlex® PRO:

HemCon® ChitoFlex® PRO is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins

Over-The-Counter-Use

HemCon® Bandage PRO OTC:

The HemCon® Bandage OTC is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions and in patients on anticoagulation therapy. The HemCon Bandage OTC also provides an antibacterial barrier against a wide range of gram positive and gram negative organisms

HemCon® Strip First Aid PRO:

The HemCon® Strip First Aid PRO is indicated for the local management of bleeding wounds such as minor cuts, minor lacerations and minor abrasions and in patients on anticoagulation therapy. The HemCon Bandage OTC also provides an antibacterial barrier against a wide range of gram positive and gram negative organisms.

VI. Comparison of Technological Characteristics with the Predicate Device:

The HemCon® Bandage PRO, HemCon® Bandage PRO OTC, HemCon® Patch PRO, HemCon® Strip PRO, HemCon® Strip First Aid PRO, and HemCon® ChitoFlex® PRO are technologically similar to the predicate device. At a high level, the subject and predicate devices are based on the following same technological elements:

- External dressing
- Single use
- poly-β-(1-4)-N-acetyl-D-glucosamine polysaccharide (chitosan) composition
- Polysaccharide solid matrix freeze phase-separated and freeze-dried dressings
- Hemostatic indication for use
- Effective for bleeding control in anti-coagulated patients
- Provides an antibacterial barrier
- Sterile – Gamma-irradiated
- Prolong contact (temporary)
- Non-implantable
- Biocompatible

VII. Performance Data:

Biocompatibility

The biocompatibility evaluation of The HemCon Bandage family of products was conducted in accordance with International Standards ISO-10993 -10, ISO 10993-5, ISO 10993-11, and USP <30>: 2007: Section 88 Biological Reactivity Tests, In Vivo Implantation. The battery of tests included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity

The HemCon Bandage family of products are considered dressings for prolonged contact (24 hours to 30 days) with breached or compromised tissue surfaces. The HemCon Bandages dressings are recommended to be removed within 48 hours.

Antibacterial Barrier

Antibacterial testing on the HemCon® Bandage family for end of shelf life efficacy was conducted using a modified version of the AATCC Test Method 100-2004 “Antibacterial Finishes on Textiles – Assessment of”. The results show a log reduction of 4.0 or greater achieved on all of the organisms tested supporting the antibacterial barrier claim. Only single strains of most species listed below have been studied.

Organisms Included in Antibacterial Testing

- *Acinetobacter baumannii* – ATCC 15308
- *Enterococcus faecalis* (VRE) - ATCC 700802
- *Enterococcus faecalis* (VRE) - ATCC 51299
- *Moraxella catarrhalis* – ATCC 8193
- *Shigella* species – ATCC 11126
- *Staphylococcus aureus* MRSA - ATCC 33591
- *Staphylococcus aureus* MRSA - ATCC BAA-1556
- *Staphylococcus epidermis* – ATCC 12228
- *Streptococcus pneumoniae* – ATCC 10015
- *Streptococcus pyogenes* – ATCC 19615

Animal Studies

To evaluate the efficacy of HemCon® Bandages in anticoagulated populations a prospective randomized open label study in 9 heparinized sheep was conducted. Both superficial femoral arteries were catheterized with 8F sheaths for 5 minutes before application of a HemCon® Bandage 2” x 2” dressing or standard manual compression. Angiography was used to confirm hemostasis at the artery. Time to hemostasis were recorded for both groups.

Hemostasis time in the HemCon group was significantly less than the control. This animal study demonstrated the HemCon Bandage’s ability to control bleeding in an anticoagulated model.

Clinical Performance Data

To further evaluate the efficacy of HemCon® Bandages in anticoagulation populations two clinical studies were conducted.

An interventional, open label prospective investigation of the efficacy of HemCon® ChitoFlex® dressing in control of complicated epistaxis in twenty subjects on anticoagulant therapy was conducted. The control was a polyvinyl acetal (PVA) nasal sponge. The study included eleven patients on antiplatelet Aspirin; four subjects on antiplatelet Clopidogrel; seven subjects on anticoagulant Warfarin; three subjects on antiplatelet Aspirin + Clopidogrel; two subjects on Warfarin + Clopidogrel + Aspirin, four subjects were on no anticoagulants or anti-platelets. Subjects discontinued anticoagulation and antiplatelet treatments after chitosan dressing application. Success was defined as achieving active control of bleeding before subject leaves the physician's office and absence of rebleeding after dressing removal at 48 hrs.

HemCon® Bandage nasal packaging was performed with 19 out of 20 subjects achieving immediate hemostasis (time to hemostasis was defined as the time interval between insertion of the nasal pack and complete cessation of bleeding). The dressings were removed at 48 hours without rebleeding or evidence of any adverse events such as adhesions, scarring, or infection.

The second clinical study was an interventional, randomized open label study with a primary endpoint of time to hemostasis with HemCon® Bandage vs. control (standard pad). Seventy subjects were treated with HemCon and sixty six were treated with control. Catheterization was with a 6 Fr sheath and subjects were anticoagulated with 2500 u of heparin. Forty-one of seventy HemCon treated subjects were on antiplatelet Aspirin while forty of sixty six control subjects were on Aspirin. Fifteen of seventy HemCon treated subjects used the anti-platelet Clopidogrel while eight of the sixty six control subjects were on Clopidogrel. Secondary endpoints included vascular complication rate and patient satisfaction.

Time to hemostasis with HemCon Bandage was lower ($p < 0.001$). Minor hematoma was lower with HemCon Bandage 4 vs 9, but not statistically significant ($p = 0.14$).

VIII. Conclusion:

The conclusions drawn from the technological characteristics and performance data support the Hemcon® Bandage PRO, HemCon® Bandage PRO OTC, HemCon® Patch PRO, HemCon® Strip PRO, HemCon® Strip First Aid PRO, and HemCon® ChitoFlex® PRO devices as safe and effective as the predicate devices. The non-clinical performance testing for antibacterial effectiveness documents the subject devices' ability to perform as intended in the specified use conditions. The animal and clinical studies demonstrate the subject devices' ability to perform in terms of suitability for anticoagulated populations