



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 31, 2015

CoreLeader Biotech Company, LTD.
Ms. Ya-Wen Kuo
Manager, Regulatory Affairs
19F Build B, No. 100, Sec 1 Xintai 5TH Road
New Taipei City, 22102
Taiwan (R.O.C.)

Re: K151204
Trade/Device Name: CoreLeader HEMO-Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 13, 2015
Received: July 16, 2015

Dear Ms. Kuo:

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)

K151204

Device Name

CoreLeader HEMO-Bandage

Indications for Use (Describe)

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

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.

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510(k) Summary

Submitted by: Coreleader Biotech Co., Ltd.
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Contact Person: Ya-Wen Kuo

Date Prepared: 2014/03/19

Proprietary Name: CoreLeader HEMO-Bandage

Common Name: Topical hemostasis wound dressing

Classification: Unclassified

Classification
 Name: Dressing, Wound, Drug

Predicate Device:

1. HemCon Chitoflex surgical wound dressing (HemCon Medical Technologies, Inc): K080818
2. QuikClot® Hemostatic Dressing, as known as QuikClot® Combat Gauze (Z-Medica, LLC): K123387
3. Celox Gauze PRO/OTC (Medtrade Products Ltd): K113560

Device Description:

CoreLeader HEMO-Bandage is woven gauze made of chitosan fiber and rayon fiber. Chitosan is a type of organic polysaccharide carrying positively-charged ions. Appearing light yellow color and inheriting biodegradability and biocompatibility of chitosan, CoreLeader HEMO-Bandage achieves hemostasis by attracting erythrocytes to the injured sites and facilitates blood clot formation. CoreLeader HEMO-Bandage is sterilized by gamma-ray radiation to 10^{-6} SAL after packed in a foil bag. With the softness and flexibility, it is readily conformable to various wound shapes.

Indications for Use:

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

Substantial equivalence:

The safety and efficacy of CoreLeader HEMO-Bandage wound dressing are substantially equivalent to the predicate devices, including HemCon Chitoflex surgical wound dressing (HemCon Medical Technologies, Inc, K080818) and QuikClot® Hemostatic Dressing, as known as QuikClot® Combat Gauze (Z-Medica, LLC, K123387), in the aspect of the mode of action, dressing form, indications for use,

biocompatibility, sterilization degree and hemostasis efficacy.

- 1 **Indications for use:** Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.
- 2 **Mode of action in hemostasis:**
Similar to HemCon Chitoflex and Celox Gauze, the effective ingredient of CoreLeader HEMO-Bandage that helps stop bleeding is chitosan, which facilitates hemostatic activity.
- 3 **Form:**
Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage appears as flat sheet of gauze with various sizes to fit in different shape of wounds.
- 4 **Materials:**
Chitosan: Similar to HemCon Chitoflex surgical wound dressing, CoreLeader HEMO-Bandage uses chitosan to facilitate hemostasis activity.
Rayon: Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage incorporates a textile in addition to effective ingredient to form the gauze dressing.
- 5 **Non-clinical tests**
 - 6.1 **Sterility:** Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage is sterilized to 10^{-6} SAL using gamma ray. The sterilization validation tests meet the criteria of AAMI / ANSI / ISO 11137-1, -2: 2006.
 - 6.2 **Biocompatibility:** CoreLeader HEMO-Bandage is as biocompatible as all the predicates.
 - 6.2.1 **Cytotoxicity:** CoreLeader HEMO-Bandage passes *in vitro* cytotoxicity test required in AAMI / ANSI / ISO 10993-5.
 - 6.2.2 **Skin irritation test:** CoreLeader HEMO-Bandage passes *in vivo* rabbit skin irritation test required in AAMI / ANSI / ISO 10993-10.
 - 6.2.3 **Skin sensitization:** CoreLeader HEMO-Bandage passes *in vivo* guinea pig

skin sensitization test required in AAMI / ANSI / ISO 10993-10.

6.3 Performance:

6.3.1 Water absorption: As the above mentioned predicate devices, CoreLeader HEMO-Bandage is fluid absorbent.

6.3.2 Hemostasis achievement: CoreLeader HEMO-Bandage is capable of stop bleeding due to the nature of chitosan. CoreLeader HEMO-Bandage is proved to achieve arterial hemostasis in *in vivo* swine femoral arterial hemorrhage model.

7 Directions to use: The direction of use of CoreLeader HEMO-Bandage is similar to those of HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze. CoreLeader HEMO-Bandage should be directly packed or pressed against the bleeding wounds until the hemostasis is achieved. Proper saline irrigation should be applied when removing CoreLeader HEMO-Bandage from the wound.

Table 1. The list of non-clinical tests conducted to validate the safety and efficacy of CoreLeader HEMO-Bandage to achieve the indications as claimed.

Test	Result	Guidance
Sterilization validation tests	CoreLeader HEMO-Bandage is sterile to 10 ⁻⁶ SAL after gamma radiation.	AAMI / ANSI / ISO 11137-1, -2: 2006
<i>In vitro</i> cytotoxicity test	No cytotoxicity	AAMI / ANSI / ISO 10993-5:2009
<i>In vivo</i> guinea pig skin sensitization test	No skin sensitization	AAMI / ANSI / ISO 10993-10: 2010.
<i>In vivo</i> rabbit skin irritation test	No skin irritation	AAMI / ANSI / ISO 10993-10: 2010.
<i>In vivo</i> systemic toxicity test	Non-systemic toxic	AAMI / ANSI / ISO 10993-11: 2006.
Heavy metal residue test	Free of heavy metal contamination	Journal of AOAC International, 2006; 89(6): 1447-66
Fluid absorption rate	CoreLeader HEMO-Bandage is water absorbent.	EN 13726-1:2002 —Part 1
Tensile strength	CoreLeader HEMO-Bandage is tensile resistant.	In-house protocol
<i>In vivo</i> hemostasis test	CoreLeader HEMO-Bandage	In-house protocol

	can temporarily control moderate to severe bleedings resulted from traumatic or surgical wounds.	
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Table 2. A comparison of non-clinical testing results of CoreLeader HEMO-Bandage with the predicate devices

	Proposed device	Predicate device		
	CoreLeader HEMO-Bandage	HemCon® Chitoflex	CELOX Gauze PRO	QuikClot® Combat Gauze
K number	K141198	K0808018	K113560	K123387
Indications	CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe bleeding resulted from traumatic or surgical wounds.	QuikClot® Combat Gauze is intended to use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.	CELOX Gauze PRO is indicated for minor wound control, including control of minor external bleeding and exudate from sutures and/or surgical procedures	Rx indication: Hemostatic dressing for temporary control of severely bleeding wounds intended for emergency use.
Mode of action	Chitosan attracts erythrocytes and facilitates hemostasis.	Chitosan attracts erythrocytes and facilitates hemostasis.	Chitosan attracts erythrocytes and facilitates hemostasis.	Kaolin initiates blood coagulation
Sterilization	Gamma radiation to 10 ⁻⁶ SAL	Gamma radiation	Gamma radiation	Gamma radiation
Cytotoxicity test	Negative	Negative	Negative	Negative

Skin irritation test	Negative	Negative	Negative	Negative
Skin sensitization test	Negative	Negative	Negative	Negative
Systemic toxicity test	Negative	Negative	Negative	Negative
<i>In vivo</i> swine hemostasis test	Achieve hemostasis of femoral artery hemorrhage < 10 minutes.	Facilitate hemostasis	Facilitate hemostasis	Facilitate hemostasis

Substantial Equivalent Statement

Based on the comparison of intended use, design, mode of actions, and performance, CoreLeader HEMO-Bandage is substantial equivalent to its predicate devices.