K102946

1/2

510(k) Summary

MAY 2 0 2011

Submitted by: Coreleader Biotech Co., Ltd.
19F, No. 100, Sec. 1, Sintai 5th Rd., Sijhih, Taipei,
Taiwan, 22102
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Contact Person: Teeming Tsao

Date Prepared: September 20, 2010

Proprietary Name: Coreleader Colla-Pad

Common Name: Collagen Wound Dressing

Classification: Unclassified

Classification Name: Topical Wound Dressing Pad

Predicate Device: INTEGRA LIFESCIENCES CORP., K072113,
INTEGRA FLOWABLE WOUND MATRIX.
INTEGRA LIFESCIENCES CORP., K081635,
INTEGRA MESHED BILAYER WOUND MATRIX.
MAXIGEN BIOTEQ INC., K100927, SurgiAid Collagen Wound Dressing

Device Description: Coreleader Colla-Pad is comprised of a porous matrix of cross-linked bovine collagen. Colla-Pad is made of highly absorbent material that converts to a soft, gel sheet that stays in intimate contact with the wound bed as it absorbs exudate t. The moisture held around the wound by Colla-Pad could provide a favorable wound healing environment. Coreleader Colla-Pad is easy to cut and apply. Cut to fit any size of acute or chronic wounds with light to heavy exudate.

K102946 2/2

Coreleader Colla-Pad is a sterile topical wound dressing, packed in a foil pouch and a foil package and sterilized by r-ray radiation to a 10^{-6} SAL.

Intended Use:

Coreleader Colla-Pad is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds, (donor sites/grafts, post-Mohs surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds.

Technological Characteristics:

Coreleader Colla-Pad is made of a porous matrix of cross-linked bovine collagen. It is through physical cross-linking process that the Colla-pad has high biocompatibility and structure is not destroyed. In addition, Coreleader Colla-Pad is made of high absorbent material that converts to a soft, gel sheet that stays in intimate contact with the wound bed as it absorbs exudate. The moisture held around the wound by Colla-Pad could provide a favorable wound healing environment.

The Coreleader Colla-Pad is biocompatibility. It has been tested and shown on accumulative effects, no evidence of delay hypersensitivity、non-cytotoxicity and is non-irritant. Coreleader Colla-Pad that is according to ISO 10993-11 Test for systemic toxicity, we could conclusion that the blood analysis and histological analysis results show test materials do not induce inflammation reaction of all test animals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY 2 0 2011

Coreleader Biotech Co., LTd
% Mr. Ian Li
19F, No. 100, Sec. 1, Sintai 5th Rd, Sijhih City
Taipei 22102
Taiwan

Re: K102946
Trade/Device Name: Coreleader Colla-Pad
Regulatory Class: Unclassifed
Product Code: KGN
Dated: May 2, 2011
Received: May 2, 2011

Dear Mr. Li:

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.

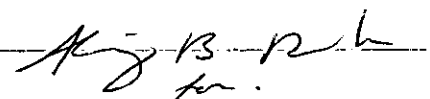
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102946

Indications for Use Statement

510(k) Number (if known):

Device Name: Coreleader Colla-Pad

Indications for Use:
Coreleader Colla-Pad Wound Dressing is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds, (donor sites/grafts, post-Mohs surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds.

Prescription Use _YES_ AND/OR Over-The-Counter Use _NO_
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102946