



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

KeriCure Incorporated
% Mr. Jonathan Ward
AJW Technology Consultants Incorporated
445 Apollo Beach Boulevard
Apollo Beach, Florida 33572

Re: K131384
Trade/Device Name: KeriCure™ Advanced Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class I
Product Code: KMF
Dated: June 27, 2014
Received: July 1, 2014

Dear Mr. Ward:

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

510(k) Number (if known): K131384

Device Name: KeriCure™ Liquid Bandage, KeriCure Natural Seal™ Liquid Bandage

Indications for Use:

To help cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

Page 1 of 1

510(k) Number (if known): K131384

Device Name: KeriCure™ Advanced Liquid Bandage

Indications for Use:

To cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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Jiyoung Dang -S

Page 1 of 1

510(k) SUMMARY
(as required by 807.92)

Regulatory Correspondent: AJW Technology Consultants, Inc
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Submitter of 510(k): KeriCure Inc
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Wesley Chapel, FL 33544
Kerriann Greenhalgh
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Date of Summary: June 25, 2014

Trade/Proprietary Name: KeriCure™ Liquid Bandage, KeriCure Natural Seal™ Liquid Bandage, KeriCure™ Advanced Liquid Bandage

Classification Name: Liquid Bandage

Product Code: KMF

Indications for use: KeriCure™ Liquid Bandage and KeriCure Natural Seal™ Liquid Bandage: To help cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions.

KeriCure™ Advanced Liquid Bandage: To cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions.

Device Description: The KeriCure™ Liquid Bandage family of products is comprised of a protective, elastic polymer film (proprietary polyacrylate polymer). As applied to the skin, the liquid bandage is slightly more viscous than water and sets within minutes to form a clear,

breathable and completely transparent film. The Liquid Bandage is capable of adhering to both intact and compromised body tissue. The device is available with either a dropper or spray applicator.

Predicate Device(s):

K083913 – NUVADERM – Chesson Labs
K991920 – Dermaphylyx Hydrophilic Wound Dressing, Dermaphylyx, Inc.

Biocompatibility Testing:

The KeriCure™ Liquid Bandages passed biocompatibility testing requirements according to ISO 10993-10 for irritation and skin sensitization. Additionally, cytotoxicity testing was performed according to 10993-5. The liquid bandage devices available in the spray applicator passed cytotoxicity testing with a score of 1.

Shelf Life:

KeriCure™ Liquid Bandages are provided non-sterile. Shelf-life testing and microbial barrier testing has been performed according to ISO11737-1, ASTM F1980, USP-51 and USP-35. The results of these tests indicate that the KeriCure™ Liquid Bandages are safe and effective for use over a 12 month period.

Performance Testing:

Performance testing for KeriCure™ Liquid Bandages was performed according to the following standards: ASTM 570, ASTM D638-10, ASTM D789, E96/ E96M-10. The applicant device passed all testing requirements with results similar to the predicate devices in terms of performance capabilities.

Substantial Equivalence:

The liquid bandages have the same fundamental technological characteristics as the predicate devices in that they are all flexible wound management devices that provide a moisture barrier, have absorptive qualities, and provide protection from infection. Test results have confirmed substantial equivalence in design, materials and intended use, and confirmed there are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.