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2445 South Alston Ave
Durham, NC 27713
(919) 281-4080 *Phone*
(919) 281-4070 *Facsimile*

MAY 11 2010

510(k) Summary

Submitter of the Application

Name:	River's Edge Pharmaceuticals, LLC
Address:	5400 Laurel Springs Pkwy Building 500 Suwanne, GA 30024
Phone:	(770) 886-3417
Fax:	(770) 886-3917

Contact for the Application

Company:	Gorbec Pharmaceutical Services, Inc. 2445 S. Alston Ave Durham, NC 27713
Contact Name:	Matthew Popp
Phone:	(919) 281-4080
Fax:	(919) 281-4077
Email:	matthewpopp@gorbec.com

Date of Summary

12 March 2010

Trade Name

BariRep

Common name

Hydrogel wound dressing

Device Classification

21 CFR 878.4022 "Dressing, Wound, Hydrogel"
Class I Non-Exempt, NAE.

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Gorbec
PHARMACEUTICAL SERVICES INC.

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Substantial Equivalence / Predicate Device

Gorbec Pharmaceutical Services Inc. believes that this submission for BariRep is substantially equivalent to the currently approved device, cleared under K083721, approved 08 January 2009.

Device Description and Design

BariRep is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for over-the-counter use. The product is formulated as an oil-in-water emulsion containing a cross-linked polyacrylic acid polymer, natural gum, and cellulose as thickening agents. The oil composition of BariRep is composed of glyceride, squalane, lecithin, and fatty acids.

Intended Use of the Device

BariRep's intended use is to manage minor burns, minor abrasions, minor cuts and minor lacerations.

Technological Comparison to Predicate Device

The device is identical in formulation, specifications and performance characteristics. It is being presented for over-the-counter use.

Non-Clinical Performance Data

N/A

Conclusion

The product's ingredients and performance characteristics have remained unchanged and are therefore, identical to the predicate. Tests and performance data are not applicable as the product remains safe, effective and substantially equivalent to the predicate. Over the counter use will not result in any increased risk to the patient.

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

Gorbec Pharmaceutical Services, Inc.
% Sandra R. Kircus, Ph.D.
Regulatory Affairs Specialist
24458 South Alston Avenue
Durham, North Carolina 27713

MAY 11 2010

Re: K100839
Trade/Device Name: BariRep
Product Code: FRO
Dated: March 15, 2010
Received: March 24, 2010

Dear Dr. Kircus:

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

Indications for Use

510(k) Number (if known): K100839

Device Name: BariRep

Indications for Use:

BariRep's intended use is to manage minor burns, minor abrasions, minor cuts and minor lacerations.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kyone for MXM

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

510(k) Number K100839