4 510(K) SUMMARY

K130900

Applicant:	Ethicon Inc. on behalf of Omrix biopharmaceuticals Ltd. P.O. Box 151 Route 22 West Somerville, NJ 08876 USA Phone: +1-908-218-2478 Fax: +1-908-218-2595
Contact Person:	Shikha Gola
Date:	March 29, 2013
Trade Device Name:	EVICEL™ Application Device
Common Device Name:	Piston Syringe
Classification:	Class II, FMF
Predicate Devices:	EVICEL Application Device (K090162)
Manufacturer:	Omrix biopharmaceuticals Ltd.

AUG 13 2013

Description of the Device Subject to Premarket Notification:

The EVICEL Application device is a sterile single use device used to apply the two biological components of the EVICEL® Fibrin Sealant (Human). Accessory tips are also provided separately to help provide the user different options for various clinical uses. The pressure regulator (Class I, Exempt) may also be provided as an accessory to help reduce the pressure of the gas obtained from a CO_2 source to within the recommended range for use.

Indications for Use:

The EVICEL™ Application Device is intended for the simultaneous topical application of the two biological components of EVICEL® Fibrin Sealant via dripping (no air pressure) or via spraying (CO_2 pressure only, utilizing the pressure regulator unit) onto the surface.

Summary of Technological Characteristics of New Device to Predicate Devices:

There are no changes to the principle of operation and fundamental scientific technology of the proposed device is equivalent to the predicate device; the device is exactly the same as the current EVICEL Application device. The only change to the new device is a modified Indications for Use Statement and an addition of a contraindication.

Conclusion:

Since there are no changes to the device design, principles of operation and fundamental scientific technology, we conclude that the proposed device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 13, 2013

Ethicon Incorporated on behalf of Omrix Biopharmaceuticals Limited
Ms. Shikha Gola
Manager, Regulatory Affairs
Route 22 West
SOMERVILLE NJ 08876

Re: K130900
Trade/Device Name: EVICEL™ Application Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 28, 2013
Received: July 1, 2013

Dear Ms. Gola:

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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 INDICATIONS FOR USE STATEMENT

510(k) No (if known): K130900

Device Name: EVICEL™ Application Device

Indications for Use:

The EVICEL™ Application Device is intended for the simultaneous topical application of the two biological components of EVICEL® Fibrin Sealant via dripping (no air pressure) or via spraying (CO_2 pressure only, utilizing the pressure regulator unit) onto the surface.

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

FDA

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130900