



Ethicon Inc.  
Attention: Sally Wixson, VMD, MS, RAC  
P.O. Box 151  
Route 22 West  
Somerville, New Jersey 08876

**Substantially Equivalent**  
January 26, 2018

Re: BK170138

Trade/Device Name: EVICEL™ Laparoscopic Airless Spray Accessory (35cm Rigid)  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: MZM  
Common Name: Fibrin Sealant Preparation Device  
Dated: October 30, 2017  
Received: October 31, 2017

Dear Dr. Wixson:

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: CBER 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Wilson W. Bryan, MD  
Director  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research

Enclosure

## Indications for Use (CBER/OTAT)

510(k) Number (if known): BK170138

Device Name: EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid)

Indications for Use:

The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) is intended to be used with the EVICEL™ Application Device for the simultaneous topical application of the two biological components of EVICEL® Fibrin Sealant (Human) onto the surface.

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CBER, Office of Tissues and Advanced Therapies

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Office Sign-Off  
Office of Tissues and Advanced Therapies

510(k): BK170138