K083354

510 (K) SUMMARY

JUL 20 2009

Submitted by: Adhezion Biomedical LLC
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Contact Person: Richard G. Jones
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Date of Summary: July 14, 2009

Device Trade Name: FloraSeal Microbial Sealant

Common or Used Name: Microbial Sealant

Classification Name: Surgical Drape and Drape Accessory
Product Code: NZP

Predicate Device: Integuseal Microbial Sealant

Device Description: Flora Seal Microbial Sealant is a film forming, cyanoacrylate based microbial sealant provided in a ready to use applicator. Each applicator consists of a thermoformed blister tray with a heat sealed lid with an attached applicator sponge tip. This applicator tray with sponge tip is contained in an outer Tyvek pouch.

Indications for Use

FLORASEAL™	Microbial Sealant is intended for use after topical operative skin preparations, with standard surgical draping, and prior to a surgical incision. The product is used to reduce the risk of skin flora contamination throughout a surgical procedure.

Substantial Equivalence: FloraSeal is substantially equivalent to IntegüSeal. This is based on comparable dispensing application design, same indication for use, bench, in vitro bacterial immobilization studies as well as clinical study, plus animal and clinical studies for both efficiency and safety including biocompatibility.

The clinical test included volunteer subjects who participated in a washout period of 14 days prior to the evaluation for stabilization of skin bacterial flora. The test site was the right inguinal region where FloraSeal and Povidone – Iodine were applied and evaluated for indigenous bacterial immobilization at 15 minutes, 4 and 24 hours. The treatments reduced microbial colonization by 99.9% within 15 minutes of application and maintained this reduction for 24 hours.

Other Testing: Bench test were preformed with Integuseal as control and showed FloraSeal to provide results that were equal to or better than Integuseal. These test included effect on wound closure strength, film integrity over time, flexibility properties (FloraSeal significantly better), MVTR, setting time, surface coverage, hydrostatic pressure and water impact penetration.

The following criteria have been met for the releasable 510(k) Summary

- **The summary includes only the information that is also covered in the body of the 510(k)**
- **The summary does not contain any puffery or unsubstantiated labeling claims.**
- **The summary does not contain any raw data, i.e., contains only summary data.**
- **The summary does not contain any trade secret or confidential commercial information.**
- **The summary does not contain any patient identification information.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard G. Jones
Senior Vice President Regulatory Affairs,
Quality Assurance and Clinical Affairs
Adhezion Biomedical LLC
One Meridian Boulevard, Suite 1B02
Wyomissing, Pennsylvania 19610

JUL 20 2009

Re: K083354
Trade/Device Name: FloraSeal Microbial Sealant
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: NZP
Dated: June 18, 2009
Received: June 18, 2009

Dear Mr. Jones:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083354

Device Name: Flora Seal Microbial Sealant

Indications For Use:

Flora Seal™ Microbial Sealant is intended for use after topical operative skin preparations, with standard surgical draping, and prior to a surgical incision. The product is used to reduce the risk of the skin flora contamination throughout a surgical procedure.

Prescription Use __X__ AND/OR Over-The-Counter Use_____

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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