K030032

510(k) SUMMARY

MAR 21 2003

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Date Summary was Prepared:

March 2003

Name of Device:

Crosseal™ Application Device

Identification of Predicate Devices:

Duploject™
Baxter Healthcare Corporation, Hyland Immuno
K973510

Mixject® Dispensing Pin with Detachable Vial Holder
Medimop Medical Projects, Ltd. (Israel)
K963583

Tissomat® and Spray Set
Baxter Healthcare Corporation, Hyland Immuno
K981089

Description of Device:
The Crosseal™ Application Device is a sterile, single-use, disposable two-syringe device used for the application by dripping or spraying of the two biological components of Crosseal™ Fibrin Sealant onto the surface of the liver in patients undergoing liver surgery. . The two syringes are connected to either a dual (non-spraying) or tri-lumen (spraying) catheter. The device also has two Mixject Dispensing Pins with Detachable Vial Holders, a device that has already been cleared by the FDA through Premarket Notification [510(k)]. The Mixject is used to attach the glass vials containing the biological components for transfer into the syringes without the use of needles. For spraying, the Application Device must be connected through an air tube with a sterile filter to a supply of pressurized gas (compressed air,

nitrogen, CO_2) via a pressure regulator, which is an accessory to the Application Device. For dripping, the Application Device can be used with or without pressurized gas. The device is ethylene oxide (EtO) sterilized.

Intended Use:

The Crosseal™ Application Device is intended for the simultaneous topical application of the two biological components of Crosseal Fibrin Sealant via dripping (no air pressure) or via spraying (utilizing the pressure regulator unit) onto the surface of the liver in patients undergoing liver surgery.

Similar Technical Characteristics between Crosseal Application Device and Duploject®

Characteristic	Crosseal™ Application Device	Duploject®
Indications	Intended for use in the simultaneous delivery of the two solutions of Crosseal™ Fibrin Sealant onto the surface of the liver in patients undergoing liver surgery.	Intended for use in the simultaneous delivery of two non-homogeneous fluids or solutions onto a surgical site.
Syringe Volume	1.0 mL, 2.0 mL, and 5.0 mL	0.5/1.0 mL, 2.0 mL, and 5.0 mL
Delivery Accuracy	The slide bar on the syringe holder ensures delivery of equal amounts of the contents of the syringes.	The slide bar on the syringe holder ensures delivery of equal amounts of the contents of the syringes.
Syringe Assembly	Syringes preassembled into syringe holster. Syringe pistons yoke-coupled.	Syringes preassembled into syringe holster. Syringe pistons yoke-coupled
Method of drawing solutions into syringes	Mixject Dispensing Pin with Detachable Vial Holder	Syringe needles
Catheter Tip	Tri-lumen tip configuration, Malleable cannula	Bi-lumen tip configuration, malleable cannula
Use	Single-use, disposable for hospital use	Single-use, disposable for hospital use
Sterilization	EtO	EtO

Similar Technical Characteristics between Crosseal™ Application Device and Tissomat® and Spray Set

Characteristic	Crosseal™Application Device	Tissomat® and Spray Set
Indications	Intended for use in the simultaneous application by dripping or spraying of the two components of Crosseal™ Fibrin Sealant onto wound surfaces.	Intended for use in the simultaneous application by spraying of the two components of Tisseel Fibrin Sealant onto wound surfaces.
Gas Supply	Compressed air, nitrogen, or CO_2	Compressed air, nitrogen, or CO_2
Spraying distance	10 to 15 cm	Minimum of 10 cm
Recommended gas pressure	2 to 3 bars (30 to 40 psi)	Maximum of 2 bars (28.5 psi)

Performance Information:
Use of the spray application technology is supported by performance testing studies that determined the optimal gas pressure range and the optimal distance that the spray catheter is required to be from the surgical tissue surface to obtain uniformity of mixing and consistency of spray spread. The optimal gas pressure (34psi) and optimal spray distance 10-15 cm was evaluated in two U.S. pivotal Phase III clinical trials. There were no adverse events associated with this system and the clinical studies demonstrated that this is an efficacious method of providing optimal coverage of fibrin sealant onto the surgical tissue surface.

Summary of Biocompatibility Tests:

- A Primary Skin Irritation Evaluation was conducted using a test extract of the device. Under the conditions of the test, the test article extract was found to not produce skin irritation.

- A Guinea Pig Maximization was performed using a test extract of the device. Under conditions of the test, the Test Article, extracted in normal saline, was found to not produce sensitization.

- A Cytotoxicity Test (MEM Elution Test) was performed using a test extract of the device. Under conditions of the test, the Test Article was found to be non-cytotoxic.

- An Acute Systemic Toxicity Test was conducted using a test extract of the device. Under conditions of the test, there was no reaction of the mice to the Test article when observed at intervals of a period of 72 hours following treatment.

- A Pyrogenicity Test (Limulus Test)-Materials Mediated, was performed using a test extract of the device. Under conditions of the test, the Test Article was found to be non-pyrogenic.
- Two studies were conducted to determine hemocompatibility: an *in vitro* hemolysis study (modified ASTM – Direct Contact Method) and a determination of clotting time using the Lee-White Method. The studies revealed that the test article was non-hemolytic, and did not biologically effect the clotting time.

Conclusions:
The intended use, design, materials of fabrication and performance of the Crosseal™ Application Device are substantially equivalent to both the Duploject and the Tissomat and Spray Set. Differences in spray parameters (spray distance, pressure) have been justified through both laboratory performance testing and human clinical trials. It is concluded that the Crosseal™ Application Device is substantially equivalent to these legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

OMRIX Biopharmaceuticals, Incorporated
Ms. Sue Bhadare
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Re: K030032
Trade/Device Name: Crosseal Application Device
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMI
Dated: January 3, 2003
Received: January 3, 2003

Dear Ms. Bhadare:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

510(k) Number:

Device Name: Crosseal™ Application Device

Classification: Class II

Product Code: 80FMF, Piston Syringe

Indications for Use:
The Crosseal™ Application Device is intended for the simultaneous topical application of the two biological components of Crosseal™ Fibrin Sealant via dripping (no air pressure) or via spraying (with air pressure utilizing the pressure regulator unit) onto the surface of the liver in patients undergoing liver surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucenta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030032

Prescription Use ✓ or Over-the-Counter Use _____
(Per 21 C.F.R. 801.109)