

K973510

DEC - 8 1997

510(k)
Summary of Safety and Effectiveness
Duploject®

Submitter

Immuno- US, Inc.
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Date summary was prepared

Spetember 16, 1997

Name(s) of the device

Duploject®

Identification of predicate device(s)

Duoflo Dispenser
K872565
Manufactured by Hemaedics, Inc.

RMI Dual Fluid Irrigating Syringe
K964833
Manufactured by Research Medical, Inc.

Surgical Sealant Dispenser (SSD)
K881020
Micromedics, Inc.

Description of the device

The Duploject® is a single-use, disposable syringe, which is used in the application of two non-homogenous fluids or solutions onto a surgical site. The Duploject® consists of two disposable syringes and withdrawal needles for reconstitution of the solutions. It also contains the following components for use in the simultaneous application of the two solutions: a clip, with a common plunger, is used to join the two identical disposable syringes together and ensures that equal volumes of the two components are fed through a common joining piece and mixed prior to dispensing. Three extra application needles and one extra joining piece are included in the package to use as replacements, if needed. The Duploject® is sterile and non-pyrogenic.

Intended Use

The Duploject® is intended for use in the simultaneous delivery of two non-homogenous fluids or solutions onto a surgical site. The Duploject® is equipped with syringe holder, which assures controlled, accurate dispensing, and a needle holder, which allows the contents of the syringes to mix prior to dispensing.

Comparison of device characteristics to predicate

Characteristic	Duploject®	Predicate Devices
Principle of Operation	A joining piece, with a common plunger, connects two disposable syringes, and the contents are mixed in a common tip prior to dispensing.	Same
Volume	0.5/1.0 ml, 2 ml, 5 ml	Same
Delivery Accuracy	The slide bar on the syringe holder ensures delivery of equal amounts of the contents of the syringes.	Same
Reuse	Disposable	Same
Sterilization	EtO (10 ⁻⁶)	Same

Conclusion

The intended use, design, materials of fabrication, and performance of the Duploject® are the same as the predicate devices. Therefore, the Duploject® is substantially equivalent to piston syringes marketed in interstate commerce prior to May 28, 1976.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

David West, Ph.D.
Senior Technical Advisor
Immuno-U.S., Incorporated
C/O Medical Technology Consultants
15825 Shady Grove Road, Suite 90
Rockville, Maryland 20850

Re: K973510
Trade Name: Duploject (0.5/1.0 ML, 5.0 ML)
Regulatory Class: II
Product Code: FMF
Dated: September 16, 1997
Received: September 16, 1997

Dear Dr. West:

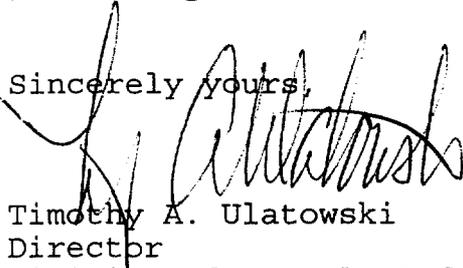
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510k Notification

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5.0 INDICATIONS FOR USE

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Roberta Cuervo
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973510

Prescription Use
(Per 21 CFR 801.109)