

OCT 8 1999

K992351

PREMARKET NOTIFICATION

510(k) SUMMARY

(As Required by 21 CFR 807.92)

Submitter Name: BioSurgical Corporation

Contact:

Terry E. Laas
Executive Vice President and
Chief Operating Officer
5990 Stoneridge Drive, Suite 112
Pleasanton, CA 94588
Phone: (925) 734-3009 Fax: (925) 737-1859

Device Name: Sealouette™ Fibrin Sealant Applicator

Common/Usual/Classification Name: Piston Syringe

Devices to which Substantial Equivalence is Claimed: Immuno-U.S. Duploject®
and BioSurgical Corporation Multi Chamber Suction Syringe

Description of the Device:

The Sealouette™ Fibrin Sealant Applicator is intended for the mixing and delivery of fibrin sealant for medical applications. It can also be attached to standard hospital wall suction for removal of fluid debris, excess tissue or foreign particles in the wound.

The Sealouette™ Fibrin Sealant Applicator consists of the main housing, which holds the dual chamber syringe barrel and a common plunger that provides for the delivery and mixture of equal volumes of the two-part fibrin sealant through a mixing chamber and application lumen.

Intended Use:

For the mixing, and one-to-one (1:1) delivery, of fibrin sealant for medical applications. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the wound.

Summary of Comparison to Predicates:

The Sealouette™ is substantially equivalent to the Duploject® in intended use, fluid sealant type, design and technological characteristics, components and materials.

The Sealouette™ suction system design is precisely the same as that of the predicate device, BioSurgical's Multi Chamber Suction Syringe cleared under #K964597.

Both the BioSurgical Sealouette™ and the Immuno-U.S. Duploject® are intended for use in the delivery of fibrin sealant. Both devices achieve the delivery of the fibrin sealant by use of a dual-chamber syringe with a mechanical plunger. Both devices incorporate a housing body, syringe, plunger, and applicator tip. Both devices provide intra-device sealant mixing immediately prior to exiting the application lumens: the Sealouette™ using an impingement mixing geometry, the Duploject® using a Y-configuration (see Mixing Design Comparison below). Where the Duploject® uses a blunt needle tip, the Sealouette™ uses a polypropylene cannula.

Discussion of Non-Clinical Tests:

A battery of non-clinical tests have been performed which demonstrate the functions of the device, and establish equivalence to the predicates in terms of: accuracy and volume of fibrin sealant delivered; the ability of the device to accurately and reproducibly deliver each component of the fibrin sealant at a fixed, predetermined ratio; and the ability of the device to homogeneously mix the components of the fibrin sealant. In addition, tests have been performed to demonstrate the substantial equivalence of the fibrin sealant delivered by the device to that delivered by the predicate in terms of: the time needed for the fibrin sealant to clot and achieve stable physical properties; the physical characteristics and geometry of the clot produced. Testing has demonstrated that the characteristics of the clot are not adversely affected by the delivery device itself or mode of delivery.

Conclusions Drawn from Non-Clinical Tests:

The Sealouette™ is substantially equivalent to the Duploject® and the Multi Chamber Suction syringe in terms physical components, technological characteristics, performance, fibrin sealant delivery, and characteristics of the fibrin sealant after delivery.



(Signature)

Terry E. Laas

(Typed Name)

July 12, 1999

(Date)

K992351

(Premarket Notification (510(k))Number)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jeffrey M. Cohen
President and Chief Executive Officer
BioSurgical Corporation
5990 Stoneridge Drive, Suite 112
Pleasanton, California 94588

Re: K992351

Trade Name: Sealouette™ Fibrin Sealant Applicator
Regulatory Class: II
Product Code: FMF
Dated: July 12, 1999
Received: July 14, 1999

Dear Mr. Cohen:

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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market notification submission does not affect any

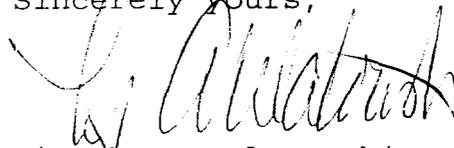
Page 2 - Mr. Cohen

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) 594-4692. 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

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K 99 2351

Device Name: Sealouette™ Fibrin Sealant Applicator

Indications For Use

For the mixing, and one-to-one (1:1) delivery, of fibrin sealant for medical applications. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the wound.

Page 12

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)

Patricia Ciccone

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992351