Attachment A

SMDA Summary of Safety and Effectiveness Information

In compliance with requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of the safety and effectiveness information for this 510(k) premarket notification.

Applicant: Haemacure Corporation
Two North Tamiami Trail
Suite 802
Sarasota Florida 34236

Product: Haemacure HemaMyst Surgical Applicator System

Description: The Haemacure HemaMyst Surgical Applicator System consists of an air regulator that can be coupled with compressed gasses present in the operating suite, a foot pedal to control air flow; and a spray head that can be coupled to currently available dual syringe applicators with a filtered air line to connect the base unit to the applicator spray head.

The base unit with the regulator and foot pedal is provided non-sterile and sold as a reusable device.

The spray head and filtered gas tubing is ethylene oxide (EtO) sterilized and sold as a sterile, single-use device.

Predicate Device Identification: A claim of substantial equivalence of the Haemacure HemaMyst Surgical Applicator System is made to the following predicate device:

Biosurgical, Corp. Multi Chamber Suction Syringe; 510(k) Number K964597. (Also marketed as the Biosurgical Sealouette System)

Marketed by: BioSurgical Corporation
5990 Stoneridge Drive
Suite 112
Pleasanton, California 94588
Phone: (925) 737-1851
Fax: (925) 737-1859

Summary of Performance Testing of the Haemacure HemaMyst Surgical Applicator System:

> Performance (functionality) testing shows that the Haemacure HemaMyst Surgical Applicator System (HSAS) is substantiantialy equivalent in performance to the Biosurgical, Corp. Multi Chamber Suction Syringe (Sealouette) at comparable air pressure.

Summary of Characteristic Comparison of the Haemacure HemaMyst Surgical Applicator System (HSAS) to the Biosurgical, Corp. Multi Chamber Suction Syringe (Sealouette):

Characteristic	Haemacure	Biosurgical, Corp.
Model	HemaMyst Surgical Applicator System (HSAS)	Multi Chamber Suction Syringe (Sealouette)
Fluid Applicator Tip	Separate aerosol head that attaches to a dual syringe applicator	Same
Compressed Air Source	Compressed air or nitrogen from the operating theater	Same
Gas Tubing Line	1/8" PVC with luer fitting	Same
Indications for Use	Application of FDA approved fluids to wounds, the delivery of antibiotics, and other wound treatment fluids. It can also be used for the application of two non-homogeneous fluids to the surgical site	Same
Sterilization of Disposable	EtO	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2000

Ms. Elaine Whitmore
Vice President, Regulatory Affairs
Haemacure Corporation
One Sarasota Tower, Suite 802
Two North Tamiami Trail
Sarasota, Florida 34236

Re: K994023
Trade Name: Haemacure HemaMyst Surgical Applicator System
Regulatory Class: II
Product Code: FMF
Dated: March 8, 2000
Received: March 14, 2000

Dear Ms. Whitmore:

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 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 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) 594-4690. 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

Attachment B

Indications for Use Statement

510(k) Number (if known): K 994023

Device Name: Haemacure HemaMyst Surgical Applicator System

Indications for Use:

Haemacure HemaMyst Surgical Applicator System is indicated for the application of two non-homogeneous fluids or solutions to the treatment site.

(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 ____
(Per 21 CFT 801.109)

Patricia Cuccia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994023