DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Chief Mediator and Ombudsman
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

February 5, 1999

[redacted]

RE: Request for Designation
Sealouette™ Sealant Applicator
Our File: RFD 98.018

Dear [redacted]

We have completed our review of the above-referenced request for designation, submitted by you on behalf of BioSurgical Corporation. BioSurgical's initial request was received in this office August 14, 1998, and filed August 17, 1998. Additional submissions were made to the file September 29, 1998, October 6, 1998, October 22, 1998, November 3, 1998, and November 13, 1998. Further information was submitted November 18, 1998, when we met with you, [redacted], and Mr. David Sierra, BioSurgical's Vice President of Research and Development. A final written submission was made yesterday, February 4, 1999.

By agreement, the period for agency review of the designation request has been extended to allow us to meet with you and fully consider the issues raised at the meeting and in your various submissions.

The Sealouette™ Applicator is described in the designation request as a multi-lumen piston syringe. The product has been the subject of two previous 510(k) premarket notifications. On September, 8, 1997, the Center for Devices and Radiological Health (CDRH) cleared the product for the mixing and application of FDA-approved fluids to wounds, the delivery of antibiotics, and other wound treatment fluids (K964597). [redacted]

[redacted]

The pending request for designation covers the use of the Sealouette™ Applicator for use in mixing and delivering fibrin glue. The request asks for reconsideration of [redacted] Contending that the product

"is simple in design and is similar to currently marketed dual chamber syringes, including those intended to deliver fibrin sealants," the request recommends reassigning the product to CDRH, and asks that the agency affirm that the product may be reviewed under a 510(k).

We have carefully considered the information provided by BioSurgical and discussed the issues raised with CBER and CDRH senior staff. We have concluded that primary review responsibility for the product will be assigned to CDRH. In addition, we are advised that CDRH will conduct its review of the product under a 510(k) premarket notification.

Our decision takes into account the fact that certain dual barrel syringes promoted for use in delivering fibrin sealants have been cleared by CDRH, and are currently marketed. In addition, this decision reflects our view that issues about the use of dual barrel syringes for use with commercially available fibrin sealant products may adequately be addressed through the 510(k) mechanism.

BioSurgical has expressed some flexibility regarding the labeling of the product for use in mixing and delivering fibrin glue. In BioSurgical's initial submission last August, the company stated that the product would be "[ ]. Later, responding to our discussions about the possible implications of "[ ]" statement, the company stated that it would be willing to label the product for use in delivering "fibrin sealants generally, and not [ ]." See BioSurgical letter of October 6, 1998. Although specific labeling is the province of the centers and the review process, we do not expect that the formulation of an appropriate indication statement for the product will be problematic. We suggest, however, that the company seek early guidance from CDRH on the matter. This office will remain involved in those discussions, as appropriate.

The Division of Dental, Infection Control, and General Hospital Devices (DDIGD), in the Office of Device Evaluation, CDRH, will have principal responsibility for conducting the review. The Division will conduct its review in consultation with CBER staff, as appropriate. For further information, contact Ms. Patricia Cricenti, Branch Chief, General Hospital Devices, DDIGD (HFZ-480), CDRH, 9200 Corporate Blvd., Rockville, MD 20850.

If you have any questions about this letter, please contact Steve Unger, of this office, at (301) 827-3390.

Sincerely yours,

Amanda Bryce Norton

Amanda Bryce Norton
Chief Mediator and Ombudsman