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 10, 1999

Curtis Miller
President
Micromedics, Inc.
1285 Corporate Center Drive -#150
Eagan, MN 55121

Re: Jurisdictional determination
FibriJet Surgical Sealant Applicator [ ],
Our File: RFD 98.022

Dear Mr. Miller:

We have concluded our review of the jurisdictional issues raised by Micromedics' recent [ ] The determination concerns the jurisdictional assignment and classification of the product when intended for use with commercial fibrin glues.

The product is a dual syringe applicator that is designed to deliver two liquids simultaneously. Micromedics has previously received 510(k) clearances for use of the device in dispensing autolgous fibrin glues (k883338, k881020, and k940371). Micromedics is now seeking FDA clearance to market the same device for use with commercially available fibrin sealants, such as Tisseel™ VH Fibrin Sealant, distributed in the United States by Baxter Healthcare Corporation, [ ]

Micromedics [ ]. As discussed in my letter to you dated September 9, 1998, the 510(k) raised a question as to whether the product was properly assigned to CDRH or should be reassigned to the Center for Biologics Evaluation and Research (CBER). The September letter also indicated that the 510(k) raised a question as to whether the 510(k) premarket notification process was the appropriate review mechanism for market clearance of the product for its new intended use. Because the 510(k) raised questions about product classification and assignment, FDA's jurisdictional regulation in 21 CFR Part 3 applied. In accordance with the provisions of that regulation, the review of the 510(k) was suspended for the period of time needed to complete the jurisdictional determination.

The September letter invited Micromedics to submit further information pertinent to the jurisdictional questions. Micromedics responded with additional information in a letter dated October 2, 1998.

We have reviewed the information submitted by the company and have discussed the jurisdictional questions with senior staff in CBER and CDRH. Based on that review, we are designating CDRH as the agency component with primary responsibility for the premarket review of the product for its new use. The product will be subject to review under the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the "Act"). Further, we are advised by CDRH staff that review may proceed under the 510(k) premarket notification procedures of the Act.

The assignment of the product to CDRH takes into account the fact that the FibriJet Sealant Applicator and other dual syringe applicators have previously been cleared for market by CDRH for various uses, including use in administering fibrin sealants. We also note that the specific applicator currently made available with the commercially licensed fibrin sealant product was initially cleared for market under a 510(k). Finally, the jurisdictional decision reflects our view that issues about the use of dual syringe applicators may adequately be addressed through the 510(k) premarket notification process.

The Division of Dental, Infection Control, and General Hospital Devices (DDIGD), Office of Device Evaluation, CDRH, will have principal responsibility for reviewing the product. 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 Boulevard, Rockville, MD 20850 (301- 443-8879). Please include a copy of this letter in your initial submissions to CDRH.

If you have any questions about this letter, please call me at 301-827-3390.

Sincerely yours,

Steven H. Unger
Deputy, Office of the Chief Mediator and Ombudsman

cc: Pat Cricenti