DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7
(301) 443-1306

Food and Drug Administration
Rockville MD 20857

January 4, 1993

Ms. Marlene Wright
P.O. Box 993
266 Queensbury Avenue
Glens Falls, NY 12801

Re: Request for Designation: Pulse Spray Injector
Our File: RFD 92-29

Dear Ms. Wright:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on November 5, 1992.

The Pulse-Spray Injector is [redacted]

It is intended to provide a [redacted]

After considering the information provided in the above-referenced request and in our meeting of December 2, 1992, and after conferring with the three affected centers, I am designating the Center for Devices and Radiological Health (CDRH) as the agency component with primary jurisdiction for the premarket review and regulation of AngioDynamic's Pulse-Spray Injector. This product will be regulated under device provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c et seq.). The Division of General and Restorative Devices in CDRH will be the primary reviewing division. For further information, please contact Ms. Amalie C. Mattan, Chief, General Hospital Devices Branch, (HFZ-410), DGRD, at (301) 427-1184.

CDRH will consult with the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research on issues relating to the safety and effectiveness of the therapeutic solutions to be delivered by the Pulse-Spray Injector. Accordingly, you may be requested to provide information about the drug and biological products that are likely to be used with your device.

If you have any other questions concerning this matter, please

do not hesitate to telephone me or the deputy, Steven Unger, at (301) 443-1306.

Sincerely,

Amanda B. Pedersen

Amanda B. Pedersen
Product Jurisdiction Officer

cc: Ms. Amalie C. Mattan