KFD 95-14

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

July 21, 1995

Ms. Diane Jachinowski
Director, Regulatory Affairs
Aradigm Corporation
26219 Eden Landing Road
Hayward, California 94545

Re: SmartMist™ Asthma Management System
Our File: RFD-95-14

Dear Ms. Jachinowski:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on May 22, 1995. The SmartMist™ Asthma Management System is a portable, battery-operated accessory to a metered dose inhaler (MDI). The product is prescribed unfilled, and is indicated for the measurement of peak expiratory flow rate of separately prescribed inhaler medications. According to the request, SmartMist™ is used without modification to the MDI; it does not affect the aerosolization process and does not introduce flaps, springs, or other moving parts into the inspiratory flow path. The request also notes that the system does not change the dose or route of administration of the delivered medication.

Aradigm recommended that primary responsibility for the premarket review and regulation of SmartMist™ be assigned to the Center for Devices and Radiological Health (CDRH), and that the product be reviewed and regulated under the premarket notification requirements of Section 510(k) of the Act (21 U.S.C. § 360(k)).

After considering the information provided in the above-referenced request, and consulting with appropriate agency officials in CDRH and the Center for Drug Evaluation and Research (CDER), I am in substantial agreement with Aradigm's recommended disposition of this combination product. Therefore, I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of SmartMist™. The product will be regulated under the premarket notification requirements of Section 510(k) of the Act (21 U.S.C. § 360(k)).

The Division of Cardiovascular, Respiratory & Neurological Devices (DCRND) in CDRH will be the primary reviewing division, and will consult with CDER as necessary. For further information, please contact Mr. Arthur A. Ciarkowski at CDRH, DCRND, HFZ-450, Anesthesiology and Defibrillator Group, 9200 Corporate Boulevard, Room 130M, Rockville, MD 20850, or by telephone at (301) 443-8320. Please include a copy of this letter with your next communication to that division. Submissions to CDRH should be addressed to the Document Mail Center (HFZ-401), 9200 Corporate Boulevard, Rockville, MD 20850.

If you have any questions regarding this matter, please contact Mr. Steve Unger or Ms. Andrea Chamblee, of this office, at 301-443-1306.

Sincerely yours,

Amanda B Pedersen

Amanda B. Pedersen
Chief Mediator and Ombudsman