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

March 18, 1994

Mr. Steven Lieberman
Vice President Quality
Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512

re: Request for Designation
Viringe Catheter Flush Device
Our File: RFD-93-15

Dear Mr. Lieberman:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on November 10, 1993. Vital Signs agreed to extend the designation deadline to March 18, 1994, to provide an opportunity for a January 31, 1993 meeting between FDA and Vital Signs officials and counsel and to permit FDA to consider additional materials submitted by the firm on February 14, 1994, and supplemented on February 25, 1994.

The Viringe Catheter is a plunger syringe containing heparin lock flush solution. The product is intended to be used to deliver heparin lock flush solution for the maintenance of patency of indwelling catheters. Vital Signs recommends that the Center for Devices and Radiological Health (CDRH) be given primary jurisdiction for the premarket review and regulation of the product, and that the product be regulated under the device authorities of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 360c et seq.

After considering the information provided in the above-referenced request, the January 31, 1994 meeting between FDA and the firm, the February 14, 1994 submission, the February 25, 1994 supplementary materials, and consulting with appropriate agency officials in the Center for Drug Evaluation and Research (CDER) and CDRH, I am in substantial agreement with Vital Signs' recommended disposition of this product. Therefore, I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of the Viringe Catheter Flush Device. The product will be regulated under the device provisions of the Act, 21 U.S.C. § 360c et seq. CDRH will consult with CDER, as appropriate.

Please submit a copy of this letter in your initial submission to CDRH. The Division of General and Restorative Devices, in CDRH will be the primary reviewing division. For further information, please contact Timothy A. Ulatowski, Acting Director for Pilot Device Evaluation Staff, at 301-594-1287.

If you have any other questions concerning this matter, please telephone Steven Unger, of this office, at 301-443-1306.

Sincerely yours,

Amanda B. Pedersen
Product Jurisdiction Officer

cc: Timothy A. Ulatowski
[ ] Esq.