DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7

Food and Drug Administration
Rockville MD 20857

April 18, 1995

Terence K. O'Brien, Ph.D.
Managing Director
LiDCo LTD
54 Ufton Road
London N1 4HH
ENGLAND

Re: Request For Designation
LiDCo Indicator Dilution Cardiac Output System
Our File: RFD-95-02

Dear Dr. O'Brien:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on February 20, 1995.

The LiDCo Indicator Dilution Cardiac Output System (LiDCo System) is a cardiac output measurement system comprised of the following components: an electronic package that contains a hand-held display, a sensor interface unit, and a blood withdrawal pump/regulator; a flow-through-cell electrode assembly; blood collection disposable and tubing; and sterile lithium chloride [ ] mmol/ml. The LiDCo System is intended for use in monitoring cardiac output and [ ] in both critically ill patients and patients with [ ] cardiovascular disease. LiDCo recommended that primary responsibility for the LiDCo System be assigned to the Center for Devices and Radiological Health (CDRH).

After considering the information submitted by LiDCo and conferring with the appropriate officials in CDRH and the Center for Drug Evaluation and Research (CDER), I concur with LiDCo's recommendation. Therefore, I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of the LiDCo System. The product will be reviewed and regulated under the device authorities of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c et seq. Any clinical investigations of the LiDCo System should be conducted in accordance with the investigational device requirements in 21 C.F.R. Part 812.

Please submit a copy of this letter with your initial submission to CDRH. The Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND) in CDRH will be the primary reviewing division, and will consult with CDER staff as necessary.

FDA recommends that LiDCo contact CDRH early in the product development process for guidance on the nature of its submission(s). Specifically, LiDCo should discuss with DCRND whether to submit a 510(k) premarket notification for some or all components of the LiDCo System. For further information, please contact Ms. Tara Ryan at the Center for Devices and Radiological Health (HFZ-452), Division of Cardiovascular, Respiratory, and Neurological Devices, 9200 Corporate Boulevard, Rockville, MD 20850, (301) 443-8243.

In addition, if this office can be of further assistance with regard to this matter, please contact Ms. Andrea Chamblee or Mr. Steven Unger at (301) 443-1306.

Sincerely yours,

Amanda B. Pedersen
Chief Mediator and Ombudsman