



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 09 2003

LiDCO Limited
c/o Mr. Gregory Speller
Quality and Regulatory Manager
16 Orsman Road
London N1 5QJ
United Kingdom

Re: K023960

Trade Name: LiDCOplus Hemodynamic Monitor

Regulation Number: 21 870.1435

Regulation Name: Single-Function, Preprogrammable Diagnostic Computer

Regulatory Class: Class II (two)

Product Code: DXG

Dated: December 17, 2002

Received: December 18, 2002

Dear Mr. Speller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

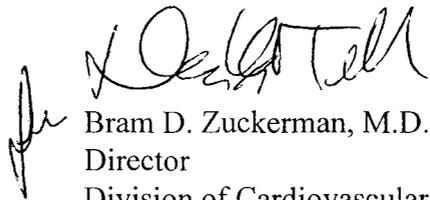
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: **LiDCO Ltd., London, U.K.**

510(k) Number (if known): **K023960**

Device Name: **LiDCOplus Hemodynamic Monitor**

INDICATIONS FOR USE:

The LiDCOplus Hemodynamic Monitor is intended for use as a diagnostic aid for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in patients greater than 88lb (40kg) in weight.

SUITABLE PATIENTS:

Patients requiring cardiovascular monitoring who have pre-inserted arterial and venous catheters and pre-existing peripheral arterial line access.

USUAL DOSE RANGE FOR CALIBRATION WITH LITHIUM CHLORIDE:

Lithium Chloride – 0.075, 0.15 or 0.3 mmol lithium chloride per cardiac output determination. The total amount of lithium chloride administered should not exceed 3mmol.

DESCRIPTION / ROUTE OF ADMINISTRATION OF LITHIUM:

Sterile lithium chloride (0.15mmol/ml, 10ml per ampoule) suitable for parenteral (i.v.) administration

DERIVED PARAMETERS:

In addition to arterial blood pressure parameters and cardiac output, the LiDCOplus Hemodynamic Monitor calculates a number of derived parameters: Body Surface Area, Systolic Pressure Variation, Cardiac Index, Stroke Volume, Stroke Volume Index, Systemic Vascular Resistance, Systemic Vascular Resistance Index, Oxygen Delivery/Index..

LOCATIONS OF USE:

Suitable patients will be receiving treatment in the following areas:

- Medical and Surgical Intensive Care Units
- Operative Suites
- Step Down / High Dependency Units
- Trauma / Accident & Emergency Departments
- Coronary Intensive Care Units
- Cardiac Catheter Laboratories

----- (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) -----

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023960

Prescription Use (Per 21CFR 801.109)

OR

Over-The-Counter Use