DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 17, 2016

LiDCO Ltd.
Eric Mills
Product Development Manager
16 Orsman Road
London, N1 5QJ GB

Re: K152935
Trade/Device Name: LiDCOunity Monitor
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG, GWQ
Dated: February 15, 2016
Received: February 16, 2016

Dear Eric Mills:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

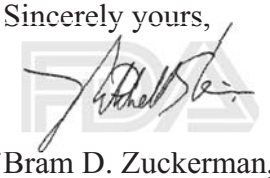
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for 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

510(k) Number (if known):_____

Device Name: **LiDCOunity Monitor**

Indications For Use:

The LiDCOunity Monitor is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use for:

1. The measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients.
2. When connected to the BIS Module: monitoring the state of the brain by data acquisition of EEG signals and may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
3. When connected to the LiDCO CNAP Module it may be used for the continuous, non-invasive monitoring of arterial blood pressure in adults and pediatric (>4yrs) patients by medical professionals. The LiDCO CNAP Module is intended for use with the LiDCOunity Monitor
4. The measurement of cardiac output via Lithium Indicator Dilution in adult patients (>40Kg/88lbs) with pre-inserted arterial and venous catheters, and for monitoring continuous blood pressure and cardiac output in patients with pre-existing peripheral arterial line access
5. In addition to arterial blood pressure parameters and cardiac output, the LiDCOunity Monitor calculates a number of derived parameters: Body Surface Area, Pulse Pressure Variation, Stroke Volume 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

Prescription Use ___X___	AND / OR	Over-The-Counter Use _____
(Part 21CFR 801 Subpart D)		(Part 21CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)