LiDCo LTD

---------- CARDIAC SENSOR SYSTEMS ----------

16 Orsman Road,
London,
N1 5QJ,
ENGLAND.

1.12 Summary of Safety and Effectiveness

Statement: This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

(i) Concept: There are numerous clinical indications for cardiac output measurement. In general, the methods are either unreliable (oesophageal Doppler, thoracic impedance), difficult to perform (indocyanine green and Fick) or hazardous (thermodilution). There has long been the need for a simple safe and reliable method. The **LIDCo System** revisits and improves the indicator dilution technique of cardiac output determination. It avoids the complications of pulmonary artery catheterisation. The **LIDCo System** will have clinical utility in patients with pre-placed arterial and venous lines, where the determination of cardiac output is required minimally invasively without the insertion of a pulmonary artery catheter

(ii) Indicator & Lithium Sensor: The lithium cation provides an excellent signal (log of concentration) against a very stable baseline in blood. The indicator is not significantly lost in its first pass to the pulmonary, or systemic circuit . The lithium cation sensor is biocompatible, thermally compensated and unaffected by changes in arterial blood pressure

(iii) Software: Despite the potential complication of secondary marker recirculation, the **LIDCo System** software has been demonstrated in a number of bench and clinical studies to calculate the area under the primary indicator dilution curve.

(iv) Accuracy: Clinical investigations show close correlation between the **LIDCo System** and current clinical standard methods:

	Patient No's	Correlation	Bias (L/Min)	Precision (L/Min)
Pulmonary Artery Catheter	51	0.963	0.19	0.38
Continuous Cardiac Output	11	0.949	0.01	0.55

(v) Safety: In most patients for whom cardiac output measurements are indicated, central venous and arterial catheters are already in place. To make a measurement with the **LIDCo System** there is no need for further cannulation with its attendant risks. Approximately 3 ml of blood are needed per determination - an insignificant amount for an adult. The dose of lithium chloride used is extremely small and has no known effects. Awake patients experience no sensation of any sort in response to the injection. Lithium pharmacology is well described in the literature with over 50 years of experience of chronic administration of high doses. **LIDCo System** dosing recommendations are conservative and make worst case assumptions - pathological compartmental volumes, accumulation of lithium, maximum dose given at maximum frequency. No side-effects/complications have been noted in critical care/post operative patient experience to date at: single doses or total doses 2-3 times final product recommendations. The **LIDCo System** reduces the risks associated with cardiac output determination compared to pulmonary artery thermodilution.

(vi) Truthful & Accurate Certification: " I certy that, in my capacity as Managing Director, I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted."

Signed by Applicant: Tennyson Date: 20/06/1996

Dr T.K. O'Brien

1.13 Comparison Tables With Predicate Devices

Table 1 Comparison of Features of the LiDCo System (CM-10;20;40 & 50) and Baxter Edwards Model 93B - 131 - 7F Flow Directed Thermodilution Catheter

CRITERIA	LiDCo SYSTEM FEATURE	BAXTER / EDWARDS MODEL 93B - 131 - 7F FEATURE
1. Registration Status		
Class 11 510 (K)	Applied for	Granted # K810352
2. Intended Use & Target Population		
(i) Intended use:cardiac output determination		Cardiac output determination & measurement of hemo-dynamic pressures in the heart and pulmonary artery
(ii) Target Population: Critical care anaesthesia and cardiology patients with pre-placed arterial and central venous lines		Critical care, anaesthesia and cardiology patients
3.Construction/Materials of:		
(i) Device Body	Flow cell moulded from polycarbonate	4 lumen radiopaque polyurethane extrusion
(ii) Sensor	Lithium ion selective electrode made from PVC membrane cast onto polyurethane	Thermistor with lead wires
(iii) Blood Bag & Tube	Blood contact material PVC - blood not returned to patient	N/A
4. Anatomical Sites		
Required location of sensor or catheter to measure cardiac output	External to body, connected to peripheral arterial line via luer lock fitting	Pulmonary artery via right side of heart

CRITERIA	LIDCo SYSTEM FEATURE	BAXTER / EDWARDS MODEL 93B - 131 - 7F FEATURE

5. Physical Safety

(i) Warnings/Complications

Clinical: Number of determinations limited to a cumulative dose of 3 mmol and worse case plasma level of 0.33 mmol/l. All injections of lithium including flushes should be noted Lithium chloride is toxic at a plasma concentration of > 1.5 mmol/l A minimum of 5 minutes should be allowed between sequential administrations of lithium chloride Waste blood/saline should not be returned to patient Avoid bolus administrations or infusions of muscle relaxants 1 hour prior to determination	**Clinical:** Rupture of the pulmonary artery resulting in vascular injury and on occasion death, carbon dioxide or air embolus, thromboembolic and infectious complications, ventricular arrhythmias, anti coagulation & antibiotic protection should be considered in cases with increased risks & when long-term catheterization (>48hrs) is necessary
Product: Loss of patency of sensor flow-through-cell due to blood clotting	**Product:**The following catheter complications may occur: kinking & knotting of catheter, stretching of body of catheter with resultant loss of electrical connection, loss of patency through blood clotting
Storage: Single use, not to be stored in direct sunlight, fluorescent or incandescent lighting conditions	**Storage:** Single use, not to be stored in direct sunlight, fluorescent or incandescent lighting conditions

(ii) Contra-Indications

Contra - indicated in: patients currently under lithium therapy for control of manic depressive psychosis, patients < 40 kg in weight	Use of thermodilution catheters is cautioned in patients with pulmonary hypertension

(iii) Biocompatability

Patient contacting Materials:	**Patient Contacting Materials:**
Polycarbonate contacts patient dermis	Polyurethane bonded with heparin - contacts directly with blood and cardiac tissues
Indicator - lithium chloride injected into blood system	Indicator - 5% dextrose or saline injected into blood system

CRITERIA	LIDCo SYSTEM FEATURE	BAXTER / EDWARDS MODEL 93B - 131 - 7F FEATURE

6. Performance

(i) Indicator detection technique

Dilution of injectate of salt solution - 0.075 to 0.3 mmol lithium chloride. 3 - 4 mls of blood sampled per cardiac output determination	Temperature based indicator 5% dextrose or saline injectate Thermistor centrally positioned no blood sample required

(iii) Clinical performance *

Clinical investigations show close correlation between the **LIDCo System** and predicate devices:

	Patient No's	Correlation	Bias (L/Min)	Precision (L/Min)
Pulmonary Artery Catheter	51	0.963	0.19	0.38
Continuous Cardiac Output	11	0.949	0.01	0.55

* See Chapter 3.3 for full results from clinical testing

Table 2 Comparison of Features of the LIDCo System Electronics Package CM-30 and Baxter Edwards Model 9520 Cardiac Output Computer

CRITERIA	LIDCo SYSTEM FEATURE	BAXTER / EDWARDS MODEL 9520 FEATURE
1. Registration Status		
	Class 11 510 (k) Applied for	Granted # K760192
2. Intended Use & Target Population		
	(i) Intended use:cardiac output determination	Cardiac output determination & measurement of hemo-dynamic pressures in the heart and pulmonary artery
	(ii) Target Population: Critical care anaesthesia and cardiology patients with pre-placed arterial and central venous lines	Critical care, anaesthesia and cardiology patients
3. Patient Safety		
	Monitor CM-31/32: • Power supply is by + 5VDC AC to DC Power Supply Unit • Connection with sensor interface is optically isolated **Blood Withdrawal Pump CM-33:** • Power supply is by battery operation (6v DC) • Low battery warning • Fail safe against arterial blood pressure • "One way" only insertion of pump tubing	**Baxter/Edwards 9520** • Battery operation 5 V DC • Recorder and digital outputs by optical circuits and transformer

CRITERIA	LiDCo SYSTEM FEATURE	BAXTER / EDWARDS MODEL 9520 FEATURE
4. Product Features		
• Dimensions & Weight	320 mm x 260 mm x 40 mm < 5 lbs	11.5 in x 3.25 in x 10.75 in < 5 lbs
• Display of CO value	Numeric in litres / minute	Numeric in litres / minute
• Possible to display dilution curve ?	Yes	Yes
• Digital output of CO ?	Yes - via RS232 port	Yes - via serial port
• Calculation method	Band-Linton derived equation involving area integration of the lithium cation dilution curve with lognormal approach - curve cut at 10% down from peak	Modified form of Stewart-Hamilton equation with area integration of thermo-dilution curve based on monoexponential approach - curve cut at 30% of peak
• Measurement range	0.1 to 20 litres / minute	0.1 to 20 litres / minute
• Self test and/or calibration possible ?	Yes	Yes
• Power source - for power supplied to CO sensor	No power is supplied; not required by LiDCo sensor	From monitor
• Battery charger/PSU	LiDCo Model CM-34 PSU 115/230 V AC, 50 - 60 hz	Edwards models 9521& 9522, 115/230 V5 AC, 50 - 60 hz battery charger

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 1999

Dr. T. O'Brien
Managing Director
LiDCO Ltd.
16 Orsman Road
London N1 5QJ
United Kingdom

Re: K962918
LiDCO System
Regulatory Class: II (Two)
Product Code: 74 DXG
Dated: October 19, 1998
Received: October 20, 1998

Dear Dr. O'Brien:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices:

General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for D A Spyh

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE: LiDCO SYSTEM for CARDIAC OUTPUT MONITORING

510(k) Number: K962918

Device Name: LiDCO System

- **Indications for Use** – Diagnostic aid (cardiac output determination). The LiDCO System is intended for the monitoring of cardiac output (blood flow in litres per minute) in patients of greater than 88 lbs (40 kg) in weight.
- **Description/Route of Administration** – Sterile lithium chloride (5 ml of 0.15 mmol/ml) suitable for parenteral (iv) administration.
- **Suitable Patients** – To operate the LiDCO System it is required that suitable patients will have available pre-placed peripheral arterial and central venous catheters.
- **Locations of Use** – Suitable patients will be receiving treatment/hospital care in the following areas:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Mark Kramer