510(k) Premarket Notification Submission (Traditional)
EDAC™ QUANTIFIER
Luna Innovations Inc. Confidential

1 510(k) Summary

MAY 17 2007

Date of Submission:
April 5, 2007

Owner Information:
Luna Innovations Incorporated
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Blacksburg, Virginia 24060
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Device Name:
Trade Name: EDAC™ QUANTIFIER
Common Name: Ultrasonic Cardiopulmonary Bypass Bubble Detector
Classification Name: Cardiopulmonary Bypass Bubble Detector (21 CFR 870.4205, Product Code: KRL)

The new EDAC™ QUANTIFIER is a device with the intended use as a standalone accessory to detect gaseous emboli in an extracorporeal bypass circuit line. It is substantially equivalent to the Sarns Ultrasonic Air Sensor that was cleared for marketing by the FDA following review of Sarns' 510(k) submission K940651.

Both the EDAC™ QUANTIFIER and Sarns Ultrasonic Air Sensor use ultrasound detection modality and therefore detect gas emboli in clear fluid and blood of all physiologic hematocrits. The Sarns Ultrasonic Air Sensor is indicated for detecting gross air emboli in the arterial return line of the cardiopulmonary bypass circuit. The EDAC™ QUANTIFIER is an improvement over the Sarns Ultrasonic Air Sensor in two key respects. The improved detection sensitivity of the EDAC™ QUANTIFIER allows for monitoring of microemboli at least 10 microns in diameter in addition to gross gas detection, while the multi-channel design allows for simultaneous monitoring of gas emboli at multiple locations on the bypass circuit.

Technological Characteristics Comparison Summary		
Characteristic	**Predicate Device: Sarns Ultrasonic Air Sensor**	**New Device: EDAC™ QUANTIFIER**
Indications	Detection of gross air bubbles in the line during extracorporeal procedures.	Detection of gaseous emboli in an extracorporeal bypass circuit line.
Contraindications	Use only as indicated.	Use only as indicated. Should not be used in procedures lasting greater than 6 hours.
Detection Modality	Through-transmission ultrasound (2 MHz)	Pulse-echo ultrasound (4 MHz)

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Technological Characteristics Comparison Summary		
Characteristic	**Predicate Device: Sarns Ultrasonic Air Sensor**	**New Device: EDAC™ QUANTIFIER**
Monitoring locations	One	Up to three simultaneously measured locations.
Arterial tubing	PVC, 3/8" x 3/32" PVC, 1/4" x 3/32" PVC, 1/4" x 1/16"	Sensors are clamped to polycarbonate connectors inserted into tubing. The connectors are available for insertion into tubing with inner diameters of 1/4", 3/8" and 1/2".
Sensitivity range	0.5 cc for 3/8" sensor 0.3 cc for 1/4" sensor	Detect emboli from 10 microns in diameter up to the diameter of the EDAC™ QUANTIFIER connector (1/2" dia.). Provides counts rates up to at least 1000/sec.
Data Provided	Real-Time On/Off alarm	Data provided for Real-time and/or Archive data of the following: Detected emboli tracks on a map with Time (x-axis) and Range (y-axis). COUNT emboli detections in the most recent 1-second interval. ESTIMATE volume of emboli detections in the most recent 1-second interval. SUM all counts and volumes detected during a measurement session to provide total and average counts and volumes. CHART the 1-second count rate and volume for the last 5 minutes. User-adjustable count and volume alarm and warning settings. Provide size distributions for a population of gaseous emboli into sizing bins of a user-selected width. Embolic load per time interval.

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Technological Characteristics Comparison Summary		
Characteristic	**Predicate Device: Sarns Ultrasonic Air Sensor**	**New Device: EDAC™ QUANTIFIER**
Flow rate	Max. of 6.0 L/min for 3/8" sensor Max. of 3.0 L/min for 1/4" sensor	2.0 L/minute - 6.0 L/minute
Company Catalog References	Sarns 5773, Sarns 5791, Sarns 5785	EDAC™ QUANTIFIER

The EDAC™ QUANTIFIER is a standalone system in which the ultrasonic sensing system consists of a three-channel ultrasonic pulser-receiver unit, a touchpanel computer, ultrasound transducers and clamps for attached the transducers to the circuit. This system is currently being certified according to voluntary medical device safety standards UL 60601-1 , IEC 60601-1-2 and IEC 60601-1-4, covering electrical device safety in medical products and IEC-60601-2-37, covering ultrasonic diagnostic safety. It also employs software and firmware to provide the embedded signal processing needed to detect gas emboli over the range of sizes described. A complete description of our software documentation and quality assurance procedures is provided as an attachment to this application.

Luna Innovations Incorporated will ensure that the EDAC™ QUANTIFIER will not be marketed for clinical use until certified to the above referenced voluntary safety standards.

The EDAC™ QUANTIFIER also employs a sterile, disposable connector that is inserted into the bypass circuit. Safety data and engineering drawings for the connector, which is a repackaged version of a 510(k) cleared connector used for oxygen saturation monitoring, is provided.

Finally, Luna has performed extensive non-clinical testing to conclude the effectiveness of the EDAC™ QUANTIFIER. Performance claims were validated on a laboratory circuit using a 28% glycerin solution to mimic the properties of blood, and on a closed loop bypass circuit using canine blood for some tests and a crystalloid solution commonly used to prime bypass circuits prior to surgery for others. Additional tests were also performed to validate functional claims such as the ability to operate over a full 6-hour surgery. The test results show that the EDAC™ QUANTIFER performs as claimed for its intended use. The tests were performed according to accepted scientific standards, as fully outlined in the System Test Plan (Attachment 5.7), and therefore substantiate the equivalence of the EDAC™ QUANTIFIER to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2007

Intertek Testing Services NA, Inc.
c/o Mr. Daniel W. Lehtonen
Responsible Third Party Official
2307 East Aurora Road, Unit B7
Twinsburg, OH 44037

Re: K071231
Edac™ Quantifier
Regulation Number: 21 CFR 870.4205
Regulation Name: Cardiopulmonary Bypass Bubble Detector
Regulatory Class: Class II
Product Code: KRL
Dated: May 2, 2007
Received: May 3, 2007

Dear Mr. Lehtonen:

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.

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 (240) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachey

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

Enclosure

Indications for Use

510(k) Number (if known): K071231

Device Name: EDAC™ QUANTIFIER

Indications for Use:

The EDAC™ QUANTIFIER has the intended use as a standalone accessory to detect gaseous emboli in an extracorporeal bypass circuit line.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071231

(Posted November 13, 2003)

Intertek ref. 500008236