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K 032871

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510(k) Summary
(As required by 21 CFR 807.92)

Submitted by:	Harry P. Gugnani L&T Medical Systems 1821 Walden Office Square, Ste 400 Schaumberg, IL 60173
Date of Summary:	August 18, 2003
Device Name:	PLANET Monitoring System
Common Name:	Cardiac Monitor
Classification Name:	Monitor, Cardiac Incl. Cardio-tachometer & Rate Alarm
Regulation Number:	21 CFR 870.2300
Product Code:	74 DRT
Predicate Devices:	Marquette Medical, Eagle 3000 K952474 Criticare, CSI Model 8100 K001020
Device Description:	PLANET is a multi-parameter Patient Monitoring System (TFT color monitor) with ECG (3 lead),Temperature,NIPB, and pulse oximetry)with an optional built-in two channel thermal array recorder which can record online data (ECG waveform and plethysmograph) along with numerical values of other parameters. PLANET is a three channel monitor with waveform display capability for ECG (3 lead), cascade and plethysmograph. It also displays the digital values of heart rate, pulse rate, SpO_2, non-invasive blood pressure (systolic, diastolic and mean) and temperature readings. It has graded and color coded alarms. It has 24 hours tabular and graphical trends for ECG, SpO_2 and temperature. It has special tabular trend for NIPB to store the last 240 readings. Alarm recall feature offers last 16 alarm conditions. Printout of tabular trend and ECG waveform can be obtained through an optional inkjet printer.
Intended Use:	The PLANET multi-parameter Patient Monitoring system is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital

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transport along with the appropriate accessories mentioned/supplied with the unit. Vital signs parameters include ECG (3 lead), Plethysmograph. It can also display the digital values of HR/PR, SpO_2, non-invasive blood pressure (systolic, diastolic and mean) and temperature readings.

The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device, which can also be used as a portable device, permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. It does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.. The monitor is not intended for home use

Technological Characteristics:	The parameters available with the PLANET Patient monitoring system (ECG-3 lead, Temperature, NIBP and Pulse oximetry) are also available with these predicate devices. The range and accuracy of the parameters & method of sensing are similar to the predicate devices. In PLANET monitor audible & visual alarms are provided similar to those in the Predicate devices. PLANET has TFT color display as does the CSI Model 8100. Planet has thermal array recorder similar to that available in Marquette Eagle 3000. Weight of the PLANET is less than that of the predicate devices. Battery (2 sealed lead acid) is provided in PLANET monitor like that of the predicate devices CSI Model 8100.
Compliance to standards:	Testing was conducted to demonstrate safety and effectiveness to the following international standards: IEC 60601-1 Medical Electrical safety IEC 60601-1-2 EMC Compliance IEC 60601-2-27 ECG safety
Conclusion:	Based on the Technological characteristics of PLANET and its comparison with the predicate devices CSI Model 8100 and the Marquette Eagle 3000 monitors, Larsen & Toubro Limited believes their device is substantially equivalent to these Monitors and does no pose any additional risk to the safety and effectiveness of the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2003

Larsen & Toubro Ltd.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K032871
Trade Name: PLANET Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 27, 2003
Received: October 28, 2003

Dear Mr. Devine:

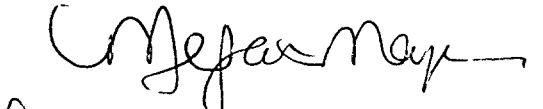
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K032871

Indication for Use statement

510(k) Number (if known) K032871

Device name : PLANET

Indication for use :

The PLANET multiparameter Patient Monitoring system is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead), Plethysmograph,. It can also display the digital values of HR/PR, SpO_2, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean) and Temperature readings.
The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device , which can also be used as a portable device, permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The arrhythmia provided is only a rate related arrhythmia without alarms. The monitor is not intended for home use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Meghan May for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032871

Prescription Use X OR Over-the –counter-use _____
(Per 21 CFR 801.109)