K061816

LARSEN & TOUBRO LIMITED

ELECTRICAL & ELECTRONICS DIVISION - ELECTRONIC PRODUCTS

Mysore Complex, KIADB Industrial Area, Hebbal - Hootagalli, Mysore - 570 018 • Tel : +91(821) 2402561 • Fax : +91(821) 2402468

E - Mail :

Ref :

JUL 1 2 2005

14th Nov 2005

510(K) SUMMARY

(Per section 807.92 ©)

CONTACT DATA			
Submitter's Name		Larsen & Toubro Limited	
Address		KIADB Industrial Area, Hebbal Hootagalli, Mysore – 570018, Karnataka, INDIA	
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Date the summary was prepared		14th Nov 2005	

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DEVICE	
Trade name	GALAXY
Common name	Patient Monitoring System
Classification name	Vital Signs Monitor

PREDICATE DEVICE IDENTIFICATION			
CFR21 Section	870.2300	**Product code (optional)**	MWI
Classification panel		Cardiovascular	
Device Class		Class II	
Legally marketed Comparison Device / K#		• Patient Monitoring System – STAR 50 (Larsen & Toubro Limited), K# K051608 • Vamos Anesthetic Gas Monitor (Draeger Medical), K# K012139	

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DEVICE DESCRIPTION

This Galaxy unit is a multiparameter Patient monitor System with an external 14 inch RGB compatible VGA monitor (640X480 pixels). The parameters provided are ECG(3/5 lead), Respiration, Temperature, NIBP, Pulse oximetry, Invasive BP and Anesthesia gas monitoring (AGM). AGM provides CO2, N2O and 5 anesthesia agents.
Galaxy is a four channel monitor with waveform display capability for ECG (Lead I / II / III / V / AVL / AVF / AVR), Plethysmograph, Respiration, Invasive Blood pressure (IBP1 & IBP2), Capnography (CO_2) & Anesthesia agents. It also displays the digital values of HR/PR, SpO_2, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$, $FiCO_2$, EtAA and FiAA readings. It has graded and color coded alarms. It has 24 hours tabular and graphical trends for all parameters except NIBP. For NIBP the last 240 readings tabular trend can be seen. Display of last 16 alarm conditions is possible in alarm recall mode. Galaxy has got an optional Thermal recorder for printing Tabular trends & waveforms.

INTENDED USE OF THE DEVICE

The Galaxy 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 (Lead I / II / III / V / AVL / AVF / AVR), Plethysmograph, Respiration, Invasive Blood pressure (IBP1 & IBP2), Capnography (CO_2) & Anesthesia agents. It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$, $FiCO_2$, EtAA and FiAA 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 monitor is not intended for home use.

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TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Device : Larsen & Toubro limited make GALAXY Patient Monitoring System.

Predicate device :

Patient Monitoring System – STAR 50, (Larsen & Toubro Limited), K# K051608
For Anesthesia Gas Monitoring - Vamos Anesthetic Gas Monitor (Draeger Medical), K# K012139

The parameters available with the predicate device Star 50 are available with the Larsen & Toubro Limited make GALAXY patient monitoring system (ECG-3/5 lead, Respiration, Temperature – 2 channels, NIBP, Pulse oximetry and Invasive BP- 2 channels). The no. of channels, range and accuracy of the parameters & method of sensing are similar to this predicate device – Star 50. In GALAXY monitor audible & visual alarms are provided similar to those in the Predicate device – Star 50
In addition, the Anesthesia gas Monitoring provided in Vamos Anesthetic Gas Monitor is available with Larsen & Toubro Limited make GALAXY Patient monitor.

Comparison of all the parameters of GALAXY to that of the predicate devices is given in the "Substantial Equivalence Equipment comparison" document.
Compliance to standards: The following international standards are referred.
Medical Electrical Equipment - General requirement for safety: IEC 60601-1
Medical Electrical Equipment General requirement for co-lateral standard Electro-magnetic compatibility requirements & tests: IEC 60601-1-2
ECG compliance: IEC 60601-2-27 & AAMI EC 13
NIBP compliance: IEC 60601-2-30 & AAMI SP10

Conclusion:
Based on the Technological characteristics of GALAXY and its comparison with those of a predicate device STAR 50 and VAMOS Anesthetic Gas Monitor (for Anesthesia Gas Monitoring), Larsen & Toubro Limited believes that their device is substantially equivalent to these Monitors and doesn't pose any additional risk on safety & effectiveness of the device.

(N Ravindran)
Head - Design & Development

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Larsen & Toubro Limited
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K061816
Trade Name: Galaxy
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (Without Arrhythmia Detection and Alarms)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: June 27, 2006
Received: June 28, 2006

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,

B Zuckerman 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

510(k) Number (if known) K061816

Device name: **GALAXY**

Indication for use:

The Galaxy 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 (Lead I / II / III / V / AVL / AVF / AVR), Plethysmograph, Respiration, Invasive Blood pressure (IBP1 & IBP2), Capnography (CO_2) & Anesthesia agents. It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$, $FiCO_2$, EtAA and FiAA 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 monitor is not intended for home use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hammerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061816