K051608

LARSEN & TOUBRO LIMITED

ELECTRICAL BUSINESS GROUP - ELECTRONIC PRODUCTS

Mysore Works, KIADB Industrial Area, Hebbal - Hootagalli, Mysore - 570 018 • Tel : (91) - 821 - 2402561 • Fax : (91) - 821 - 2402469

E - Mail :

Ref :

JUN 2 9 2005

25th April, 2004

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	
Telephone	91-821-2402561	**Fax**	91-821-2402468
Contact Person	A.B.Deshpande	**Title**	Head – Quality Assurance
E-Mail address		DeshpandeAB@myw.ltindia.com	
Date the summary was prepared		April 25th ,2004	

K051603

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DEVICE	
Trade name	STAR 50
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#		• Eagle 3000 patient Monitoring System (Marquette Electronic) / K952474 • Vital signs monitor Model 8100 (CSI) / K001020 • Patient Monitoring System - STAR, (Larsen & Toubro Limited), K# K032867	

K051682

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DEVICE DESCRIPTION

This STAR 50 unit is a multiparameter Patient monitor System (TFT color monitor) with ECG(3/5 lead), Respiration, Temperature, NIBP, Pulse oximetry, Capnography and Invasive BP.
STAR 50 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) and Capnography (CO_2). It also displays the digital values of HR/PR, SpO_2, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$ and $FiCO_2$ 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. STAR 50 has got a optional Thermal recorder for printing Tabular trends & waveforms.

INTENDED USE OF THE DEVICE

The STAR 50 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) and Capnography (CO_2). It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$ and $FiCO_2$ 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 STAR 50 Patient Monitoring System.

Predicate device :

Eagle 3000 patient Monitoring System (Marquette Electronic), K# K952474
Vital signs monitor Model 8100 (CSI), K# K001020
Patient Monitoring System – STAR, (Larsen & Toubro Limited), K# K032867

The parameters available with these predicate devices are available with the Larsen & Toubro Limited make STAR 50 patient monitoring system (ECG-3/5 lead, Respiration, Temperature – 2 channels, NIBP, Pulse oximetry, Capnography and Invasive BP- 2 channels). The no. of channels, range and accuracy of the parameters & method of sensing are similar to the predicate devices. In STAR 50 monitor audible & visual alarms are provided similar to those in the Predicate devices.
STAR 50 has got TFT color display like CSI Model 8100. Weight is also comparable with that of Marquette Eagle 3000. Battery (2 scaled lead acid) is provided in STAR 50 monitor like that of the predicate device CSI Model 8100.

Comparison of all the parameters of STAR 50 to that of the predicate devices is given in the "Substantial Equivalence Equipment comparison" document.

Compliance to standards :

The following international standards are referred.
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 STAR50 and its comparison with those of a predicate device CSI Model 8100 and Marquettee Eagle 3000 monitors, 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

JUN 29 2005

Larsen & Toubro Ltd.
c/o Mr. Ned Devine
Intertek Testing Services NA, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K051608
Trade Name: STAR 50 Monitoring System
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 16, 2005
Received: June 17, 2005

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 (240) 276-0295 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 may be obtained 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,

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): K051608

Device Name: STAR 50

Indications for Use:

The STAR 50 unit is a 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 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) and Capnography (CO_2). . It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive & Invasive Blood Pressure (systolic, diastolic and mean) and Temperature, $EtCO_2$ and $FiCO_2$ 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.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051608