K103763

MAR 1 1 2011

08th Sep 2010

510(K) SUMMARY

(Per section 807.92 ©)

CONTACT DATA			
Submitter's Name		Larsen & Toubro Limited	
Address		L & T Medical Equipment & Systems, Mysore Campus, Gate No.5, Plot No. 358 – 360, KIADB Industrial Area, Hebbal, Mysore – 570018, Karnataka, INDIA	
Telephone	91-821-2407200	**Fax**	91-821-2407001
Contact Person	A.B.Deshpande	**Title**	Head – QA & Regulatory Affairs
E-Mail address		DeshpandeAB@myw.ltindia.com	
Date the summary was prepared		8th Sep 2010	

DEVICE	
Trade name	STELLAR 300
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#		STELLAR 404T Patient Monitoring System (L&T Medical Equipments & systems) / K060058	

DEVICE DESCRIPTION

This STELLAR 300 unit is a 3 parameter Patient monitor System (TFT color monitor) with NIBP, Pulse oximetry and Temperature with an inbuilt two channel thermal array recorder for printing of Tabular trends & waveforms.
STELLAR 300 have waveform display capability for Plethysmograph. It also displays the digital values of PR, SpO_2, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean) and Temperature readings. It has graded and color coded alarms It has 2 hours and 12 hours tabular and graphical trends for SpO_2 and Temperature. It has special tabular trend for NIBP to store the last 100 readings. Alarm recall feature offers last 16 alarm conditions.

INTENDED USE OF THE DEVICE

The STELLAR 300 - three parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric and neonate patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameter includes Plethysmograph. It can also display the digital values of 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 monitor is not intended for home use.

8th Sep 2010

TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Device: Larsen & Toubro limited make STELLAR 300 Patient Monitoring System.
Predicate device:
STELLAR 404T Patient Monitoring System (Make: L&T Medical Equipments & systems) / K060058

The parameters available with the Larsen & Toubro Limited make STELLAR 300 Patient monitoring system (NIBP, Pulse oximetry and Temperature) are also available with the predicate device. The range and accuracy of the parameters & method of sensing are similar to the predicate devices. In STELLAR 300 monitor audible & visual alarms are provided similar to that in the Predicate device.

STELLAR 300 has got TFT color display like STELLAR 404T. STELLAR 300 has got thermal array recorder similar to that available in STELLAR 404T. Battery provided in STELLAR 300 is Lithium ion, which is same as that of predicate device STELLAR 404T.

STELLAR 300 device with Adult & Pediatric mode is already FDA approved – K093017. In this submission, Neonate mode is added to STELLAR 300.

Comparison of all the parameters of STELLAR 300 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 Equipment-General requirement for safety
IEC 60601-1-2 Medical Electrical Equipment-EMC requirements & tests

Conclusion:
Based on the Technological characteristics of STELLAR 300 and its comparison with that of predicate device STELLAR 404T, Larsen & Toubro Limited believes that their device is substantially equivalent to this predicate Monitor 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Larsen & Toubro Limited
c/o Mr. E.J. Smith
Smith Associates
1468 Harwell Ave
Crofton, MD 21114

MAR 1 1 2011

Re: K103763
Trade/Device Name: Stellar 300
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: March 2, 2011
Received: March 4, 2011

Dear Mr. Smith:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K103763

Device name: STELLAR 300

Indication for use:

The STELLAR 300 - three parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric and neonate patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameter includes Plethysmograph. It can also display the digital values of PR, SpO_2, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean) and Temperature readings.

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Prescription Use √ AND/OR Over-The –Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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. Vodnoy

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103763