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MAR 15 2011

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		21st January 2011	

DEVICE	
Trade name	STAR 50N
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#		• STAR 55 Patient Monitoring System (L&T Medical Equipments & systems) / K080173 • Stellar 300 Patient Monitoring System (L&T Medical Equipments & systems) / K093017	

DEVICE DESCRIPTION

STAR 50N is a multi-parameter patient monitoring system for continuous monitoring of the physiological parameters ECG (3/5 lead), Respiration, NIBP, IBP, Temperature, SpO2 and external CO2 (optional).

STAR 50N is a 6-channel monitor with 10.4" TFT display capable of displaying ECG, Respiration, Spo2, CO2, digital values of HR/PR, SpO2, RR, Non-Invasive Blood pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2 and FiCO2 readings. It has 168 Hours tabular and graphical trends. It has special feature of NIBP having a trend of storing last 240 readings. It has Alarm Recall facility with last 24 patient alarms details. It has a two-channel thermal array recorder for printing of Tabular trends & waveforms. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.
It has got optional communication features - USB, Wi/Fi (optional) and Ethernet. This monitor can also be connected to L&T Central Nursing Station (Skyline 55) and an external LCD-TFT display

INTENDED USE OF THE DEVICE

The STAR 50N multi-parameter Patient Monitoring system is intended to monitor a single adult, pediatric and 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 /5 lead), SpO2, Respiration, Temperature, external optional Capnography (CO_2). It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2, and FiCO2. This monitor can also be connected to L&T Central Nursing Station (Skyline 55) and an external LCD-TFT display.

The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Predicate Devices:

Company Name	Trade Name	510(k) Number
Larsen & Toubro LTD	Star 55	K080173
Larsen & Toubro LTD	Stellar 300	K093017

Predicate device:

Star 55 is a Multi parameter patient monitor used as a predicate device for all the parameters of Star 50N Multi parameter patient monitor, except for NIBP parameter.

Stellar 300 is a three parameter (NIBP, SpO2 & single channel Temperature) patient monitor used as a predicate device for 'NIBP parameter' of Star 50N Multi parameter patient monitor.

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

Summary of Critical Parameters

Parameter	Star 50N	Star 55
510(k) Number		K080173
Alarms	Same	Same
ECG	Same	Same
Respiration	Same	Same
Temperature	Same	Same
Pulse Oximetry	Same	Same
IBP (Invasive Blood Pressure)	Same	Same
Capnography	Same	Same

Parameter	Star 50N	Stellar 300
510(k) Number		K093017
NIBP	Same	Same

Compliance to standards:

The following international standards are referred.

IEC 60601-1 Medical Electrical safety

IEC 60601-1-2 EMC compliance

Conclusion:

Based on the Technological characteristics of STAR 50N and its comparison with that of predicate devices Star 55 and Stellar 300, Larsen & Toubro Limited believes that their device is substantially equivalent to this predicate 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Larsen & Turbo Limited
c/o Mr. E. J. Smith
Regulatory Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

MAR 15 2011

Re: K103686
Trade/Device Name: Star 50N
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: February 25, 2011
Received: February 28, 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

K103686

Indications for Use Form

Indications for Use

510(k) Number (if known): K103686

Device Name: Star 50N

Indications for Use:

The Star 50N multi-parameter Patient Monitoring system is intended to monitor a single adult, pediatric and 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 / 5 lead), SpO2, Respiration, Temperature, external optional Capnography (CO_2). It can also display the digital values of HR/PR, SPO_2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EyCO2, and FiCO2.

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman 3/15/2011

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K103686