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LARSEN & TOUBRO LIMITED

ELECTRICAL & ELECTRONICS DIVISION - ELECTRONIC PRODUCTS

Mysore Campus, KIADB Industrial Area, Hebbal - Hootagalli, Mysore - 570 018 • Tel: +91 (821) 2405000 • Fax: +91 (821) 2402468

E - Mail :

NOV 2 0 2009

Ref :

Date: 24.09.2009

510(K) SUMMARY

(Per section 807.92 ©)

CONTACT DATA			
Submitter's Name		Larsen & Toubro Limited	
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Contact Person	A.B.Deshpande	**Title**	Head – Quality Assurance & Management Representative
E-Mail address		DeshpandeAB@myw.ltindia.com	
Date the summary was prepared		24th September 2009	

DEVICE			
Trade name		**Skyline 55 Ver 1**	
Common name		Central Nursing Station or Central Monitoring System	
Classification name		Monitor, Physiological, Patient Monitor	
CFR21 Section	870.2300	**Product code**	MWI

PREDICATE DEVICE IDENTIFICATION			
CFR21 Section	870.2300	**Product code**	MWI
Classification panel		Cardiovascular	
Device Class		Class II	
Legally marketed Comparison Device / K#		• SKYLINE 55 Ver 0 / K081552 • Mindray HYPERVISOR VI / K062194	

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DEVICE DESCRIPTION

Central Nursing Station is a kind of medical information system widely applied in clinical monitoring, whose operation requires specific hardware environment such as a PC loaded with an Operating System and a software application. The loaded PC system is connected with multiple individual bedside monitors through a communication channel (In Skyline55 case wired Ethernet 802.3 and wireless 802.11bg). It can collect the monitoring information of the patient transferred via interface from the bedside monitor. It can also display and export the integrated information from bedside monitors so as to free-up doctors from clinical monitoring work and create centralized monitoring management.

The Skyline55 Ver1 is such Central Nursing Station software which is loaded in a PC of recommended specifications. The system set-up includes a FCC approved high-performance PC hardware system, the application software and Windows operation system (Windows XP). Through applying Larsen & Toubro specified protocol, the Central Monitoring System receives physiological information from cleared bedside monitors manufactured by Larsen & Toubro, includes: Planet 50, Star 50, Galaxy, Planet 55, Star 55 and Galaxy 55.

Skyline 55 Ver1 can maximally support the simultaneous interfacing of 16 bedside monitors. TCP/IP protocol is applied to ensure reliable transmission of data between the bedside monitors and the Central Nursing Station using Cat5e cable.

Skyline 55 Ver1 offers centralized display of physiological information of many patients who are monitored simultaneously. The software can support one display with display information from up to 16 bedside monitors. If any of the bedside monitors gives off a patient vital sign parameter alarm (also referred as Red Alarm), prompt information will be immediately displayed by means of audible and visual alarm for medical personnel attention.

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The physiological waveforms displayed on Skyline 55 Ver1 include: ECG, RESP, CO2, SPO2, IBP and Anesthesia agents. The physiological parameters displayed on the central monitoring system include: HR, RR, SPO2, SysDia/Mean NIBP and IBP, TEMP and CO2, Arrhythmia, ST indications and Anesthesia agents. The software also performs notification directly for Red alarms from the bedside monitor. Moreover database technology is applied to store these from the bedside monitor.

Skyline 55 Ver1 is used to provide a secondary display/announcement for the physiological parameters based on the bedside monitor and is NOT a patient monitoring device. The clinician is instructed to always reference the primary bedside monitor before making any patient care decisions.

STATEMENT OF INTENDED USE

The Skyline55 Ver 1 is Central Nursing System Software that is loaded in a PC, which in turn is connected to a listed patient monitor via an Ethernet communication (wired or wireless). The system software will enable a user to simultaneously monitor 8/16 beds. The system software will make available to the user, patient information in the form of continuous monitoring along with extended features in which 72-hour trend data can be stored for each patient and displayed in the form of Waveform recall, Graphical and Tabular Trends. Alarm records for 72-hours too are recorded and stored for each patient connected to the system software.
Skyline 55 Ver1 is intended to conduct centralized monitoring for adult, pediatric and neonatal patients' vital sign information from multiple monitors in a hospital, the monitoring parameters include ECG, NIBP, SPO2, RESP, IBP, TEMP, CO2 and Anesthesia agents.

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

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TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Skyline55 Ver1 Central Nursing Station is substantially equivalent to the currently marketed predicate devices HypervisorVI and Skyline55 Ver0 Central Monitoring System. All Skyline55 Ver1 and predicate devices HypervisorVI and Skyline55 Ver0 free-up doctors from clinical monitoring work at each bedside monitor and create centralized monitoring management. All systems get connected to bedside monitors through Ethernet interface 802.3(wired) and 802.11(wireless). The requirement of Operating system in the PC for both the software is same, which is Windows XP professional.

The notable differences between the technical specifications of Skyline 55 Ver1 and HypervisorVI are as mentioned below:

1. The PC processor (host CPU) requirement is little different; HypervisorVI requires P IV 2.0G, while Skyline55 Ver1 requires Core 2 duo processor 1.8 GHz.
2. For HypervisorVI, the maximum number of simultaneously connected and displayed monitors is 32 whereas for Skyline55 Ver1, the number is 16.
3. For HypervisorVI either 1 or 2 displays can be simultaneously connected whereas for Skyline55 Ver1, only 1 display can be connected.
4. There is no provision to connect a recorder in Skyline55Ver1 whereas HypervisoVI has provision to connect a Recorder. In Skyline55 Ver1, a standard computer printer can be connected with the PC by loading the appropriate Printer Driver and parameter trend, alarm recall and patient discharge summary can be printed on normal paper.

The notable differences between the Skyline55 Ver1 and Skyline55 Ver0 are as mentioned below:

1. ECG + 2 user selectable waveform storage for 72 hours added in Skyline55 Ver1 which is not there in Skyline55 Ver0
2. Tabular tread, graphical trend and alarm recall storage is extended up to 72 hours from 24 hours in Skyline55 Ver0
3. Monitor to CNS bi-directional patient admission is added in Skyline55 Ver1 which is not there in Skyline55 Ver0
4. ECG strip for 36 seconds for each alarm in last 72 hours is added in Skyline55 Ver1 which is not there in Skyline55 Ver0

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The detailed feature-by-feature comparison of Skyline55 Ver1 with predicate device HypervisorVI and Skyline55 Ver0 has been given in the document titled as 'Predicate Device Comparison Document'.

Conclusion:

The conclusions drawn from testing and validation of Skyline 55 Ver1 demonstrates that the device is as safe, as effective, and performs as well as the legally marketed predicate devices Skyline55 Ver0 (K081552) and the Hypervisor VI Central Monitoring System (K062194, by Shenzen Mindray Bio-Medical Electronics Co., Ltd, China)

(N. Ravindran)
Head – Design & Development

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

NOV 2 0 2009

Re: K092153
Skyline 55 Version 1
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 6, 2009
Received: October 6, 2009

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.

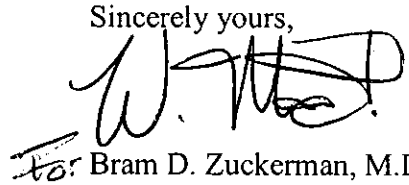
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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) K092153

Device name: **Skyline55 Ver 1**

Indication for use:

The Skyline55 Ver 1 is Central Nursing System Software that is loaded in a PC, which in turn is connected to a listed patient monitor via an Ethernet communication (wired or wireless). The system software will enable a user to simultaneously monitor 8/16 beds. The system software will make available to the user, patient information in the form of continuous monitoring along with extended features in which 72-hour trend data can be stored for each patient and displayed in the form of Waveform recall, Graphical and Tabular Trends. Alarm records for 72-hours too are recorded and stored for each patient connected to the system software.
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The user, responsible to interpret the monitored data made available, will be a professional health care provider. The system software permits patient monitoring with adjustable visible and audible alarm signals. The system software is not intended for home use.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092153