



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

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

NOV 20 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.

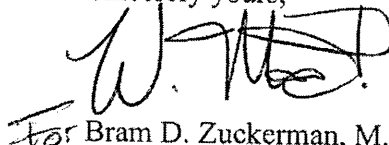
Page 2 – Mr. E.J. Smith

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" (21 CFR 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.

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.

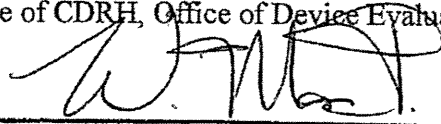
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092153