DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 14, 2016

Skanray Technologies Private Limited
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K151512
Trade/Device Name: Star 60
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: January 7, 2016
Received: January 7, 2016

Dear Yolanda 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

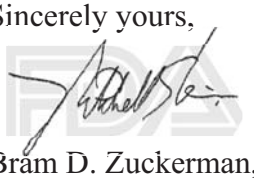
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151512

Device Name

STAR 60

Indications for Use *(Describe)*

Star 60 multi-parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric or Neonatal patient's vital signs at the bedside or during intrahospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3L / 5L), SpO2, Respiration,Temperature,NIBP, IBP and Capnography (CO2). It can also display the digital values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2, FiCO2 readings.

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(As Per 21 CFR 807.92)

SPONSOR

Company Name:	Skanray Technologies PVt Ltd Healthcare Division
Company Address:	#360, KIADB Industrial Area, Hebbal, Mysore – 570018, Karnataka, India.
Telephone:	91-821-2407202
Fax:	92-821-2407001
Contact Person:	J. Mahadevan
Summary Prepared	May 19, 2015
Trade Name:	**Star 60**
Common/Usual Name:	Patient Monitoring System
Classification Name:	Physiological Patient Monitor (without arrhythmia detection or alarms)
510(k) Number	**K151512**
Product Code:	MWI
Device Class:	Class II
Regulation Number:	21 CFR 870.2300

Predicate Device

Company	***Product***	***510(k) #***
Welch Allyn	Spot Vital Signs LXi	K101680
Philips Medical Systems	SureSigns VS4	K120132
Suntech Medicals	Cycle BP Monitor & Pulse Oximeter, Model 1060	K060820
L&T Medical & Systems	Stellar 300	K103763

Device Description

STAR 60 is a patient monitor with a wide range of communication options. Capacitive sensing buttons in keyboard is introduced. It fits in clearly to a new age of patient monitoring.

- **ECG+RESPIRATION+TEMPERATURE MODULE**: This module is divided in area and functionality between the main board and the ECG child card. The Temperature section and the DC-DC section of the ER2T lie in the main board.
- **SpO2:** This module is inbuilt inside the monitor on the main board. It is used to measure the partial pressure of oxygen in the human body.
- **NIBP:** This module is inbuilt inside the monitor on to the chassis. It is used to non-invasively measure the systolic, diastolic & mean blood pressure.
- **CO2:** This module is inbuilt inside the monitor on to the chassis. It is used to measure the level of CO2 in the blood (EtCO2 & FiCO2).
- **IBP:** STAR 60 can support IBP modules. For ease of understands we shall name as IBP1 & IBP 2. IBP 1/2 module is inbuilt on the main board. It is used to invasively measure the systolic and diastolic blood pressure.

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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.

Summary of Technological Characteristics

Star 60 is designed and developed with reference to our previous 510K cleared product
Star55 with same product code as Star60 – MWI.
These 2 products are same in terms of:
• ECG,
• Respiration,
• Temperature,
• IBP,
• NIBP,
• SpO2 and
• CO2
• Display type
• Alarm systems
• Thermal recorder / printer
• Equipment classification, applicable standards

Star60 is compared with MP70 for advanced features that are included in the Star 60 and include:
• Communication with external equipment including analog and system outputs
• Display size and resolution.

Differences between Star 60 and Star 55
The differences between the two devices includes advanced features that include:
• Number of waveform traces displayed
• Waveform display options / selections

The inclusion of the advanced features have been validated and verified to ensure that the new features do not impact performance and the safety and efficacy of the device.

Non Clinical Testing

Electrical and EMC Testing for the Star 60 included the following

IEC 60601-1-2	EMC Test Report
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
IEC 60601-1-8	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance --Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automatic cycling non-invasive blood pressure monitoring equipment.
IEC 60601-2-34	Medical electrical equipment -- Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment.
IEC 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment

Additional Performance Testing:

ANSI/AAMI EC 13	Cardiac Monitors, Heart rate Meter and Alarms
ANSI/SSMI SP10	Manual, Electronic or Automated Sphygmomanometers
IEC 62304	Medical device software – software life cycle processes (Software/Informatics)
ISO 14971	Application of risk management to medical devices

Substantial Equivalence

The Star 60 is substantially equivalent to the predicate device in Indications for Use, Materials and Design. The conclusions drawn from the non-clinical tests demonstrate that the Star 60 is as safe, as effective, and performs as well as or better than the predicate device.

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