



Food and Drug Administration  
10903 New Hampshire Avenue  
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June 17, 2015

Skarray Technologies Pvt Ltd.  
c/o Ms. Yolanda Smith  
Regulatory Consultant  
Smith Associates  
1468 Harwell Avenue  
Crofton, Maryland 21114

Re: K150512  
Trade/Device Name: Star 90  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI  
Dated: May 12, 2015  
Received: May 14, 2015

Dear Ms. 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

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)

K150512  
Page 1 of 1

Device Name  
STAR90

Indications for Use (Describe)

The STAR 90 multi-parameter Patient Monitoring system is intended to monitor a single adult, pediatric or 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 / 12 Lead), SpO2, Respiration, Temperature and Capnography (CO2) , IBP. It can also display the digital values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature , IBP , EtCO2 and 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)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

SPONSOR

Company Name: Skanray Technologies PVt Ltd  
Healthcare Division  
Company Address: Skanray Technologies PVT Ltd. No. 15-17,  
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Telephone: 91-821-2407200  
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Contact Person: Hema Singh

Summary Prepared September 5, 2014

Trade Name: Star 90  
Common/Usual Name: Patient Monitoring System  
Classification Name: Physiological Patient Monitor (without arrhythmia  
detection or alarms)  
Product Code: MWI  
Device Class: Class II  
Regulation Number: 21 CFR 870.2300

Predicate Device

| <b>Company</b>                     | <b>Product</b>                     | <b>510(k) #</b> |
|------------------------------------|------------------------------------|-----------------|
| Larsen & Toubro Ltd                | Star 55                            | K08073          |
| Philips medizin Systeme Boeblingen | Philips Intellivue patient Monitor | K093268         |

Device Description

The STAR 90 Multi-Parameter Patient Monitoring System is a Semi Modular Patient monitor with a wide range of communication options, touch screen and capacitive sensing buttons.

Modularity in this monitor is achieved by providing 3 slots wherein the parameter modules that fit into these modules are hot swappable i.e. they can be connected or disconnected from the unit without switching off the unit. The module is detected at run time. Patient monitoring modules include:

- ECG+RESPIRATION+TEMPERATURE MODULE: This module is divided in area and functionality between the interface card and the ECG child card. The Temperature section and the DC-DC section of the ER2T lie in the interface card.

- SpO2: This module is inbuilt inside the monitor on the interface card, but there is an option to jack an external SpO2 module in one of the jackable slots. It is used to measure the partial pressure of oxygen in the human body.
- NIBP: This module is inbuilt inside the monitor on the interface card. It is used to non-invasively measure the systolic and diastolic blood pressure.
- CO2: This module can be jacked into one of the jackable slots. It is used to measure the level of CO2 in the blood (EtCO2 & FiCO2). When AGM is used this module will not be available
- IBP: STAR 90 can support 2 IBP modules. For ease of understanding we shall name the 1st IBP as IBP ½ and the 2nd IBP as IBP ¾. IBP ½ module is inbuilt in the interface card, whereas the IBP ¾ can be jacked in one of the slots. It is used to invasively measure the systolic and diastolic blood pressure
- AGM: The connectivity for this module is inbuilt inside the interface card of the system, but the AGM module has to be connected through the connector provided. It is used to measure anesthesia gas concentration, CO2 and O2. This is optional module in place of CO2 module.

### Indications for Use

The STAR 90 Multi-Parameter Patient Monitoring System is intended to monitor a single adult, pediatric or 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 / 12 lead), Spo2, Respiration, Temperature and Capnography (CO2), IBP. It can also display the numeric values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean). Temperature, IBP, EtCO2 and 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.

### Summary of Technological Characteristics

Star 90 is designed and developed with reference to our previous 510K cleared product Star55 with same product code as Star90 – 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

Star90 is compared with MP70 for advanced features that are included in the Star 90 and include:

- Communication with external equipment including analog and system outputs
- Display size and resolution.

Differences between Star 90 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 90 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<br>(Software/Informatics) |
| ISO 14971       | Application of risk management to medical devices                                 |

Substantial Equivalence

The Star 90 is substantially equivalent to the predicate device in Indications for Use, Materials and Design. Safety and performance testing was performed and Skanray Technologies has concluded that the device does not introduce any significant questions of safety and efficacy and is substantially equivalent to the predicate devices.