



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 23, 2016

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

Re: K152831

Trade/Device Name: SpotSkan
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, MWI
Dated: January 19, 2016
Received: January 21, 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". It is positioned above a rectangular stamp containing the letters "FDA".

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*)

K152831

Device Name

SpotSkan,

Indications for Use (*Describe*)

SpotSkan, a multi-parameter Spot Check Device, along with the appropriate accessories mentioned / supplied with the unit, is intended to measure a single adult or pediatric (but not neonatal) patient's vital signs at the physician's clinic. SpotSkan is not a Patient Monitor.

Vital signs measured include SpO₂, Non-Invasive Blood Pressure, Pulse Rate and Temperature. A thermal recorder is provided for printing measured data. The user is responsible to interpret the measured data made available, and shall be a professional health care provider. 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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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 08, 2015

Trade Name: SPOTSKAN

Common/Usual Name: Spot Vital Signs Measurement Device

Classification Name: Noninvasive Blood Pressure System

Product Code: DXN

Device Class: Class II

Regulation Number: 870.1130

Predicate Device

<i>Company</i>	<i>Product</i>	<i>510(k) #</i>
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

SpotSkan is SKANRAY's new portable Spot Check Device, which can be used to measure SpO₂, Pulse rate, Blood Pressure non-invasively and Tympanic Temperature, for adult and pediatric (but not neonatal) patients. It is a compact device which has only numeric values displayed on a 6.5" LED Backlit TFT LCD display of resolution 640*480, containing SpO₂, NIBP, Pulse Rate and Temperature values. It has last 12 patients' readings saved. It does not have continuous monitoring capability of the parameters or any alarms.

Interface of a thermal recorder to take print out of real time measurements and values from patient history make the data availability through a hard copy. It has got battery backup of 2 hours, which enables it to continue measurement even during mains power OFF condition. User can enter patient ID, name, age, height, weight; and select mode and sex; these details can be recorded in the thermal print out.

The scope of application is in the medical diagnostics, where a general physician will use the monitors in clinics. The user is responsible to interpret the measured data made available, and shall be a professional health care provider. The monitor is not intended for home use.

Indications for Use

SpotSkan, a multi-parameter Spot Check Device, along with the appropriate accessories mentioned / supplied with the unit, is intended to measure a single adult or pediatric (but not neonatal) patient's vital signs at the physician's clinic. SpotSkan is not a Patient Monitor.

Vital signs measured include SpO₂, Non-Invasive Blood Pressure, Pulse Rate and Temperature. A thermal recorder is provided for printing measured data. The user is responsible to interpret the measured data made available, and shall be a professional health care provider. The monitor is not intended for home use.

Summary of Technological Characteristics

SpotSkan is designed and developed with reference to previous 510K cleared products as a Substantial Equivalent product.

The Technologies used and the processes followed are the same as described below and is comparable and in compliance to all the required Safety and performance standards.

Similarities:

- Spotskan is compared with Suntech Medical's Cycle BP Monitor Model 1060 for the Pulse Oximeter. SpO₂ technology and module used in these two products are same.
- Spotskan is compared with L&T Medical & Systems Stellar 300 for the NIBP technology and module used in these two products are same.
- Spotskan and Philips Medical Systems, SureSigns VS4 monitors are compared for the Tympanic Temperature thermometer technology and module used in these two products are same.
- Spotskan and Welch Allyn, Spot Vital Signs LXi monitor is compared to show equivalence for Spot Check device.

Differences:

Spotskan uses a different Power supply and Battery in comparison with predicate devices. These changes are verified and validated to confirm the performance, safety and efficacy of the device in meeting the standard requirements. Also the Power supply and Battery has got the CE and UL marking adding to the safety and performance compliance.

Non Clinical Testing

Electrical and EMC Testing for the Star 90 included the following

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 80601-2-61	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment
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.
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.

Additional Performance Testing:

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 SpotSkan 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.

Prakash U. P.

Head - Design & Development