



May 25, 2018

Skarray Technologies Pvt Ltd
% Parul Chansoria
Regulatory Consultant
Elexes
6494 Tralee Village Dr.
Dublin, California 94568

Re: K172147

Trade/Device Name: Star 65

Regulation Number: 21 CFR 870.2300

Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm).

Regulatory Class: Class II

Product Code: MWI, DRT, DSJ, DXN, DXG, DSF, DRS, CCK, FLL, NHO, CBQ, DQA, NHP, CCL,
MNR, CBS, NHQ, CBR, KRB

Dated: April 23, 2018

Received: April 27, 2018

Dear Parul Chansoria:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K172147

Device Name
Star 65

Indications for Use (Describe)

Star 65 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 with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead /5 lead), SpO2, and Respiration, Temperature, Invasive Blood Pressure (Systolic, Diastolic and Mean), Non-invasive Blood Pressure (Systolic, Diastolic and Mean), Capnography (CO2), Cardiac Output (CO) & AGM module. It can display the numeric values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, CO, EtCO2 and FiCO2, N2O, O2, EtAA and FiAA 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. It shall be used only by trained clinicians.

In addition Star 65 got Arrhythmia and ST detection from 3L/5L ECG measurements. The Arrhythmia and ST analysis module is intended for use with Adult & Pediatric patients and is not intended for use with Neonatal patients(ST and Arrhythmia detection functionality is not available for U.S.A).

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.

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SECTION 5. 510 (K) SUMMARY (AS PER 21 CFR 807.92)**I. SUBMITTER**

Skarray Technologies Pvt Ltd, Healthcare division,
#360, KIADB Industrial Area, Hebbal,
Mysore – 570018, Karnataka, India.

Contact Person: Parul Chansoria, Regulatory Consultant, Elexes
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Summary Prepared: May 23, 2018

FDA Establishment Number: 3002513440

II. DEVICE

Common/Usual Name: Patient Monitoring System
Trade Name: Star 65
Regulation Description: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Classification Panel: Cardiovascular
Primary Product Code: MWI
Regulation Number: 870.2300

Secondary Product Codes:

Product Code	Regulation Number	Regulation Description
DXN	870.1130	Noninvasive blood pressure measurement system
KRB	870.1915	Thermodilution probe
DRT	870.2300	Cardiac monitor (including cardiotachometer and rate alarm)
DQA	870.2700	Oximeter
DSJ	870.1100	Blood Pressure Alarm
DXG	870.1435	Single-function, preprogrammed diagnostic computer
DSF	870.2810	Paper chart recorder
DRS	870.2850	Extravascular blood pressure transducer
CCK	868.1400	Carbon dioxide gas analyzer
CBQ	868.1500	Enflurane gas analyser
NHO	868.1500	Enflurane gas analyzer
NHP	868.1500	Enflurane gas analyser
NHQ	868.1500	Enflurane gas analyser
CBS	868.1620	Halothane gas analyser
CBR	868.1700	Nitrous oxide gas analyser
CCL	868.1720	Oxygen gas analyser

MNR	868.2375	Breathing frequency monitor
FLL	880.2910	Clinical electronic thermometer

III. PREDICATE DEVICE

The Patient Monitoring System (Model: Star 65) is substantially equivalent to the following cleared device:

Company	Predicate Priority	Product	510(k) Number	Product Code	Regulation Number	Regulation Description
Skarray Technologies Pvt. Ltd.	Primary	Star 90	K150512	MWI	21 CFR 870.2300	Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Philips MedizinSysteme Boeblingen GmbH	Secondary	MP50	K161531	MHX	21 CFR 870.1025	Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
L&T Medical & Systems	Tertiary	Star 55	K080173	MWI	21 CFR 870.2300	Cardiac Monitor (including Cardiotachometer and Rate Alarm)

IV. DEVICE DESCRIPTION

Star 65 is a multi-parameter modular patient monitoring system for continuous monitoring of the physiological parameters like ECG (3/5 lead), Respiration, NIBP, IBP, Temperature, SpO₂, CO₂, Cardiac Output (CO), & Anesthesia Gas Monitoring (AGM) Module (Optional). The modular parameters are IBP, CO and CO₂.

Star 65 is a 8 channel monitor with 12.1" LED display with touch screen capable of displaying and monitoring ECG, Respiration, SpO₂, CO₂, IBP, and O₂ digital values of HR/PR, SpO₂, RR, Non- Invasive Blood Pressure (Systolic, Diastolic & Mean), Invasive Blood Pressure (Systolic, Diastolic & Mean), Temperature, EtCO₂, FiCO₂, IPI, CO, N₂O, O₂, EtAA, and FiAA readings.

Star 65 has 240 Hours tabular and graphical vital trend. Star 65 has a NIBP trend of last 240 readings. Star 65 has Alarm Recall facility with last 48 'Patient Alarms' details.

Star 65 has communication features like USB for Thumb drive, Printer, Bar code scanner interface, Ethernet for CNS & Bed to Bed connectivity, HDMI output for External monitor connectivity, External Port for AGM 55 interface, Wi-Fi for CNS, Bed to Bed & Network Printer connectivity. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals, high priority alarms are indicated by red colour, medium priority alarms are indicated by yellow colour & low priority alarms are represented by blue colour.

Star 65 has got Drug calculator software package to display drug dosage applied / to be applied for the standard Medicines.

V. INDICATIONS FOR USE

Star 65 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 with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead /5 lead), SpO₂, and Respiration, Temperature, Invasive Blood Pressure (Systolic, Diastolic and Mean), Non-invasive Blood

Pressure (Systolic, Diastolic and Mean), Capnography (CO₂), Cardiac Output (CO) & AGM module. It can display the numeric values of HR/PR, SpO₂, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, CO, EtCO₂ and FiCO₂, N₂O, O₂, EtAA and FiAA 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. It shall be used only by trained clinicians.

In addition Star 65 got Arrhythmia and ST detection from 3L/5L ECG measurements. The Arrhythmia and ST analysis module is intended for use with Adult & Pediatric patients and is not intended for use with Neonatal patients (ST and Arrhythmia detection functionality is not available for U.S.A).

VI. TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The monitoring of vital sign physiological parameters is the technological principle for both the subject and predicate devices. It is based on the use of modules and accessories that are either connected internally or externally to the monitors in order to monitor the specific physiological parameter.

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Device	Star 65	Star 90	MP50	Star 55	---
Indication For Use	<p>Star 65 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 with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead /5 lead), SpO2, and Respiration, Temperature, Invasive Blood Pressure (Systolic, Diastolic and Mean), Non-invasive Blood Pressure (Systolic, Diastolic and Mean), Capnography (CO2), Cardiac Output (CO) & AGM module. It can display the numeric values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, CO, EtCO2 and FiCO2, N2O, O2, EtAA and FiAA readings.</p> <p>The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device</p>	<p>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.</p> <p>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</p>	<p>The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.</p> <p>The MP50 monitors are additionally intended for use in transport situations within hospital environments.</p> <p>The monitors are only for use on one patient at a time. They are not</p>	<p>Star 55 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, Capnography (CO2), & optional Gas module unit. It can also display the digital values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure</p>	Same

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
	<p>permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use. It shall be used only by trained clinicians.</p> <p>In addition Star 65 got Arrhythmia and ST detection from 3L/5L ECG measurements. The Arrhythmia and ST analysis module is intended for use with Adult & Pediatric patients and is not intended for use with Neonatal patients(ST and Arrhythmia detection functionality is not available for U.S.A).</p>	<p>and audible alarm signals. The monitor is not intended for home use.</p>	<p>intended for home use. Not therapeutic devices. The monitors are for prescription use only.</p>	<p>(Systolic, Diastolic and Mean), Temperature, EtCO₂, FiCO₂, N₂O, O₂, EtAA and FiAA 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.</p>	
DISPLAY:					
Type	Colour TFT LCD display	Colour TFT LCD display	Colour TFT LCD display	---	Same as Star 90
Size	12.1 inch	15 inch	12.1 inch	---	Same as MP50
Resolution	1024 X 768	1024 X 768	800 X 600		Same as Star 90
No. of traces	8 traces	10 traces	6 traces		Similar to Star 90
Sweep (trace) speed	<p>12.5, 25, 50mm/Sec for ECG, SpO₂, IBP1, IBP2, IBP3 & IBP4.</p> <p>6.25, 12.5, 25mm/Sec for Respiration, AGM & Microstream Capnography</p>	<p>12.5, 25, 50mm/Sec for ECG, SpO₂ IBP1, IBP2, IBP3 & IBP4.</p> <p>6.25, 12.5, 25mm/Sec for Respiration, AGM & Microstream</p>	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
		Capnography			
Waveform display options	a) Standard Formats: 3 b) User Formats: 4 c) Auto Format d) Quick ECG format	e)Standard Formats: 3 f)User Formats: 4 g) Auto Format h) Quick ECG format	---	---	Same as Star 90
CONTROLS:					
	Front Panel: 1 switch for Unit ON / OFF. 1 switch for Alarm Acknowledgment 1 switch for NIBP start/stop 1 switch for Freeze 1 switch for Home 1 switch for Recording 1 switch for Pump on 1 switch for to set Monitor in stand-by Mode 1 switch for GOTO (Short cut Key) 1 switch for Optical encoder with switch. 1 switch for IBP zeroing	---	---	Front Panel: 1 switch for Unit ON / OFF. 1 switch for Alarm Acknowledgment 1 switch for NIBP start/stop 1 switch for Freeze 1 switch for Home 1 switch for Recording 1 switch for Pump on 1 switch for to set Monitor in stand-by Mode 1 switch for GOTO (Short cut Key) 1 switch for Optical encoder	Same as Star 55

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
				with switch. 1 switch for IBP zeroing	
ALARMS:					
Notification	Audible & visual	Audible & visual	Audible & visual	Audible & visual	Same as Star 90
Classification	<p>1. Patient Alarms : High Priority: Audio & Visual (flashing RED LED alarm) and message indication. Respective parameter values will be highlighted.</p> <p>Medium Priority: Audio & Visual (flashing YELLOW LED alarm) and message indication. Respective parameter values will be highlighted</p> <p>2. Equipment Alarms: Audio & Visual (flashing BLUE LED alarm) and message Indication</p> <p>3. Re-Alarm: 1 minute re-alarm provided in case condition persists after alarm Acknowledgment. (With User configurable Alarm Pause duration).</p>	<p>1. Patient Alarms : High Priority: Audio & Visual (flashing RED LED alarm) and message indication. Respective parameter values will be highlighted.</p> <p>Medium Priority: Audio & Visual (flashing YELLOW LED alarm) and message indication. Respective parameter values will be highlighted</p> <p>2. Equipment Alarms: Audio & Visual (flashing BLUE LED alarm) and message Indication</p> <p>3. Re-Alarm: 1 minute re-alarm provided in case condition persists after alarm Acknowledgment. (With User configurable Alarm Pause duration).</p>	---	---	Same as Star 90
Alarm Silencing /	Alarms Suspend: Continuous	Alarms Suspend:	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
mute & Alarm suspend / pause	RED LED ON to indicate alarm suspend condition with crossed bell icon on Real Time Screen	Continuous RED LED ON to indicate alarm suspend condition with crossed bell icon on Real Time Screen			
Volume	10 steps (Low to High)	10 steps (Low to High)	---	---	Same as Star 90
ECG:					
Standard leads available	3/5L	3/5L/12L	---	---	Similar to Star 90
Lead fail indication	Individual lead fault indication on screen	Individual lead fault indication on screen	---	---	Same as Star 90
Gain selection / Voltage range	5mV, 2mV, 1.3mV, 1mV, 0.5, 0.2mV & Auto - User selectable	5mV, 2mV, 1.3mV, 1mV, 0.75mV, 0.5mV, 0.2mV & Auto - User selectable	---	---	Same as Star 90
Heart rate range	20-350 BPM.	20-350 BPM.	---	---	Same as Star 90
Accuracy	2bpm or 2% whichever is greater	2bpm or 2% whichever is greater	---	---	Same as Star 90
Input impedance	>2.5 M ohms at 10Hz, &100 M ohm DC	>2.5 M ohms at 10Hz, &100 M ohm DC	---	---	Same as Star 90
Common mode rejection	<15mm (max.) (Allowable noise for 3 V p-p 20Hz sine wave)	<15mm (max.) (Allowable noise for 3 V p-p 20Hz sine wave)	---	---	Same as Star 90
Frequency response / bandwidth	Bandwidth: 3 - 40 Hz for Monitoring mode 0.05 - 120 Hz for Diagnostic mode 3 - 20HZ for OT mode	Bandwidth: 0.5 - 40 Hz for Monitoring mode 0.05 - 120 Hz for Diagnostic mode 0.5 - 20HZ for OT mode	---	---	Same as Star 90
HR ALARMS	Adjustable alarm limits Min – 20 to 320BPM.	Adjustable alarm limits Min – 20 to 320BPM.	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
	Max - 50 to 350 BPM 4 seconds delay for HR alarms	Max - 50 to 350 BPM 4 seconds delay for HR alarms			
Defibrillation protection	Yes	Yes	---	---	Same as Star 90
Pacemaker detection / rejection	When pacer is ON the monitor will display the HR for all single and double pacemaker pulses either 150 or 250 msec apart of amplitudes $\pm 2\text{mV}$ to $\pm 700\text{mV}$ from 0.5msec to 2.0 msec.	When pacer is ON the monitor will display the HR for all single and double pacemaker pulses either 150 or 250 msec apart of amplitudes $\pm 2\text{mV}$ to $\pm 700\text{mV}$ from 0.5msec to 2.0 msec.	---	---	Same as Star 90
ESU protection	Yes	Yes	---	---	Same as Star 90
RESPIRATION:					
Measurement technique	Measured either through ECG or CO2 If Capnography option is not provided then input is from ECG: impedance pneumography method.	Measured either through ECG or CO2 If Capnography option is not provided then input is from ECG: impedance pneumography method.	---	---	Same as Star 90
Respiration rate range	0-150 breaths\min.	0-150 breaths\min.	---	---	Same as Star 90
Accuracy	Up to 30, +/- 1bpm, from 30 to 60 +/-2bpm, >60 +/-4bpm.	Up to 30, +/- 1bpm, from 30 to 60 +/- 2bpm, >60 +/-4bpm.	---	---	Same as Star 90
Sensitivity	Sensitivity (max): 0.2 ohm/cm Sensitivity (min): 4 ohm/cm Excitation current: < 300 micro Amp at 50 kHz.	Sensitivity (max): 0.2 ohm/cm Sensitivity (min): 4 ohm/cm Excitation current: < 300 micro Amp at 50 kHz.	---	---	Same as Star 90
Gain	Options x1, x2, x3, x4, AUTO (user selectable). x4 is default gain level	Options x1, x2, x3, x4, AUTO (user selectable). x4 is default gain level	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Alarms	User-selectable upper and lower respiration rate limits.	User-selectable upper and lower respiration rate limits.	---	---	Same as Star 90
TEMPERATURE:					
No. of channels	Two	Two	---	---	Same as Star 90
Temperature range	0°C - 50°C	0°C - 50°C	---	---	Same as Star 90
Scale value	Displays direct readings of temperature input. 'ΔT' value displayed in place of T2	Displays direct readings of temperature input. 'ΔT' value displayed in place of T2	---	---	Same as Star 90
Accuracy	±0.2° C or ±0.4°F.	±0.2° C or ±0.4°F.	---	---	Same as Star 90
Linearity	±0.1 °C	±0.1 °C	---	---	Same as Star 90
Alarms	Temperature limits adjustable Min: 12°C to 47°C Max: 15 °C to 50°C	Temperature limits adjustable Min: 12°C to 47°C Max: 15° C to 50°C	---	---	Same as Star 90
Unit	°C or °F user selectable	°C or °F user selectable	---	---	Same as Star 90
Probe fault	Display shows 'OFF' if the probe not connected. Display shows out of range condition (-? -) in the event of short circuit or open circuit probes .	Display shows 'OFF' if the probe not connected. Display shows out of range condition (-? -) in the event of short circuit or open circuit probes.	---	---	Same as Star 90
	Out of range condition also indicate the temperature raises above 50° C falls below 10° C. If a fault is present in the temperature measuring circuit, the message 'FAULT' will be displayed.	Out of range condition also indicate the temperature raises above 50° C falls below 10°C. If a fault is present in the temperature measuring circuit, the message 'FAULT' will be displayed.	---	---	Same as Star 90
NON-INVASIVE BLOOD PRESSURE (NIBP):					
Measurement technique	Oscillometric	Oscillometric	---	---	Same as Star 90
Module Used	Suntech Advantage	Suntech Advantage	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Displayed parameters	Systolic, diastolic and mean	Systolic, diastolic and mean	---	---	Same as Star 90
Measurement	Manual, Auto & Stat mode	Manual, Auto & Stat mode	---	---	Same as Star 90
modes	In AUTO mode intervals of 2,3,4,5,10,15,30,60,90,120,240,360minutes are user selectable. In STAT mode unit will take as many readings as possible in 5minutes. Duration between measurements is 10-12 sec	In AUTO mode intervals of 2,3,4,5,10,15,30,60,90,120,240, 360minutes are user selectable. In STAT mode unit will take as many readings as possible in 5minutes. Duration between measurements is 10-12 sec	---	---	Same as Star 90
Range	20 – 250 mmHg	20 – 250 mmHg	---	---	Same as Star 90
Accuracy	+/-5mmHg with a standard deviation greater than 8 mmHg.	+/-5mmHg with a standard deviation greater than 8 mmHg.	---	---	Same as Star 90
Auto zero	Zero pressure reference is automatically established after every reading.	Zero pressure reference is automatically established after every reading.	---	---	Same as Star 90
Total cycle time	20 to 40 seconds typical	20 to 40 seconds typical	---	---	Same as Star 90
Automatic cuff deflation	Automatic deflation if : a) Cuff pressure exceeds 300mmHg in Adult & Pediatric and 150mmHg in Neonate Mode b) Measurement time exceeds 50 seconds.	Automatic deflation if : a)Cuff pressure exceeds 300mmHg in Adult & Pediatric and 150mmHg in Neonate Mode b) Measurement time exceeds 50 seconds.	---	---	Same as Star 90
Cuff inflation	Initial inflation: Adult:160mmHg Neonates:80mHg Pediatric:120mmHg Subsequent inflation approximately 30 mmHg greater than previous systolic pressure	Initial inflation: Adult:160mmHg Neonates:80mHg Pediatric:120mmHg Subsequent inflation approximately 30 mmHg greater than previous systolic	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
		pressure			
Alarms	Adjustable alarm limits (for both SYS & DIA) Upper: 30 to 250 mmHg Lower: 20 to 240 mmHg	Adjustable alarm limits (for both SYS & DIA) Upper: 30 to 250 mmHg Lower: 20 to 240 mmHg	---	---	Same as Star 90
PULSE OXIMETRY:					
Technology	Electro optical sensor (2 LEDs & a photo diode)	Electro optical sensor (2 LEDs & a photo diode)	Electro optical sensor (2 LEDs & a photo diode)	Electro optical sensor (2 LEDs & a photo diode)	Same as Star 90
Module Used	Nellcor-Nell 1	Nellcor-Nell 1			Same as Star 90
SpO2 range	1- 100%	0 - 100%	0 - 100%	0 - 100%	Same as Star 90
Accuracy:	Adults/Pediatric: (+/- 1 Std. Dev) 70-100% +/-3 digits 1- 69% : unspecified Neonates: 70-100% +/-4 digits 1-69% Unspecified	Adults/Pediatric: (+/- 1 Std. Dev) 70-100% +/-3 digits 0- 69% : unspecified Neonates: 70-100% +/-4 digits 0-69% Unspecified	---	---	Same as Star 90
Alarms	Adjustable alarm limits Min 50 to 95% Max 55 to 100%	Adjustable alarm limits Min 50 to 95% Max 55 to 100%	---	---	Same as Star 90
IBP (INVASIVE BLOOD PRESSURE):					
Input Impedance	>1MOhm	>1MOhm	---	---	Same as Star 90
Leakage Current	<10 micro Amp at 240V AC, 50Hz.	<10 micro Amp at 240V AC, 50Hz.	---	---	Same as Star 90
Processed Pressure Signals	Systolic, Diastolic and Mean.	Systolic, Diastolic and Mean.	---	---	Same as Star 90
Accuracy	2 mmHg or 2% whichever is greater.	2 mmHg or 2% whichever is greater.	---	---	Same as Star 90
Bandwidth	DC to 20Hz	DC to 20Hz	---	---	Same as Star 90
Sensitivity	5 Micro V / V /mmHg of transducers.	5 Micro V / V /mmHg of transducers.	---	---	Same as Star 90
CAPNOGRAPHY:					
Type	Micro Medico -- Micro Stream technology from Medtronic	Micro Medico -- Micro Stream technology from	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
		Medtronic			
Method	Non-depressive infra-red absorption technique	Non-depressive infra-red absorption technique	---	---	Same as Star 90
Measurement range:	Et CO2: 0 –100mmHg Fi CO2: 0 – 20mmHg	Et CO2: 0 –100mmHg Fi CO2: 0 – 20mmHg	---	---	Same as Star 90
CO2 accuracy:	0-20mins: 0-38mmHg: +/-4mmHg, 39-99mmHg: +/-12% of reading, 20mins and up: 0-38mmHg: +/-4mmHg, 39-99 mmHg: +/- 5% of reading + 0.08% for every 1mmHg (above 38 mmHg)	0-20mins: 0-38mmHg: +/-4mmHg, 39-99mmHg: +/-12% of reading, 20mins and up: 0-38mmHg: +/-4mmHg, 39-99 mmHg: +/- 5% of reading + 0.08% for every 1mmHg (above 38 mmHg)	---	---	Same as Star 90
Warm Up Time	40 Sec (Typical)	40 Sec (Typical)	---	---	Same as Star 90
RR	0– 150 bpm	0– 150 bpm	---	---	Same as Star 90
Alarms	EtCO2: High: 5-80 mmHg Low: 0-75 mm Hg FiCO2: High: 2-20 mm Hg RR: High: 10-150 bpm Low: 5-145 bpm	EtCO2: High: 5-80 mmHg Low: 0-75 mm Hg FiCO2: High: 2-20 mm Hg RR: High: 10-150 bpm Low: 5-145 bpm			Same as Star 90
Invasive Cardiac Output:					
Method	Thermo dilution Method	---	Thermo dilution Method	---	Same as MP50
Cardiac Output Range	0.1 liter /min to 20 liter /min.	---	0.1 to 20.0 l/min	---	Same as MP50
Accuracy	+5 %.	---	+5 %.	---	Same as MP50
Blood Temp.	17°C - 45 °C	---	17°C to 43°C	---	Similar to MP50
Injectate Temp.	0°C - 30°C	---	-1 to 30°C	---	Same as MP50
(Bt) and (It) Accuracy	±0.1°C	---	±0.1°C	---	Same as MP50

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
(Bt) and (It) Resolution	0.1°C	---	0.1°C	---	Same as MP50
Anesthesia Gas Monitor(AGM):					
Module Used	Artema Technology from Mindray	Artema Technology from Mindray	---	Artema Technology from Mindray	Same as Star 90 and Star 55
Identification of Anesthetic Agent	Auto/Manual	Auto	---	Auto	Similar to Star 90 and Star 55
Oxygen sensor type	Galvanic	Galvanic	---	Galvanic	Similar to Star 90 and Star 55
Measurement Range:					
EtCO2	0-80 mmHg or 0.0-10.0 kpa/vol%	0-80 mmHg or 0.0-10.0 kpa /vol%	---	0-80 mmHg or 0.0-10.0 kpa/vol%	Same as Star 90 and Star 55
FiCO2	0-20 mmHg or 0.0 - 2.6 kPa / Vol%.	0-20 mmHg or 0.0 - 2.6 kPa / Vol%.	---	0-20 mmHg or 0.0 - 2.6 kPa / Vol%.	Same as Star 90 and Star 55
RR	2-100 bpm	2-100 bpm	---	2-100 bpm	Same as Star 90 and Star 55
Measurement Accuracy					
RR	Up to 60 - +/- 1bpm, >60 unspecified	Up to 60 - +/- 1bpm, >60 unspecified	---	Up to 60 - +/- 1bpm, >60 unspecified	Same as Star 90 and Star 55
N2O	0 – 20 ±2 20 – 100 ±3	0 – 20 ±2 20 – 100 ±3	---	0 – 20 ±2 20 – 100 ±3	Same as Star 90 and Star 55
Halothene	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	---	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	Same as Star 90 and Star 55
Isoflurane	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	---	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	Same as Star 90 and Star 55
Enflurane	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	---	0 – 1 ±0.15 1 – 5 ±0.2 > 5 Unspecified	Same as Star 90 and Star 55
Sevofurane	0 – 1 ±0.15 1 – 5 ±0.2 5 – 8 ±0.4	0 – 1 ±0.15 1 – 5 ±0.2 5 – 8 ±0.4	---	0 – 1 ±0.15 1 – 5 ±0.2 5 – 8 ±0.4	Same as Star 90 and Star 55

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
	> 8 Unspecified	> 8 Unspecified		> 8 Unspecified	
Desflurane	0 – 1 ±0.15 1 – 5 ±0.2 5 – 10 ±0.4 10 – 15 ±0.6 15 – 18 ±1 > 18 Unspecified	0 – 1 ±0.15 1 – 5 ±0.2 5 – 10 ±0.4 10 – 15 ±0.6 15 – 18 ±1 > 18 Unspecified	---	0 – 1 ±0.15 1 – 5 ±0.2 5 – 10 ±0.4 10 – 15 ±0.6 15 – 18 ±1 > 18 Unspecified	Same as Star 90 and Star 55
CO2	0 – 1 ±0.1 1 – 5 ±0.2 5 – 7 ±0.3 7 – 10 ±0.5 > 10 Unspecified	0 – 1 ±0.1 1 – 5 ±0.2 5 – 7 ±0.3 7 – 10 ±0.5 > 10 Unspecified	---	0 – 1 ±0.1 1 – 5 ±0.2 5 – 7 ±0.3 7 – 10 ±0.5 > 10 Unspecified	Same as Star 90 and Star 55
O2	0 – 40 ±1 40 – 60 ±2 40 – 80 ±3 80 – 100 ±4	0 – 40 ±1 40 – 60 ±2 40 – 80 ±3 80 – 100 ±4	---	0 – 40 ±1 40 – 60 ±2 40 – 80 ±3 80 – 100 ±4	Same as Star 90 and Star 55
Resolution:					
CO2	+/-1 mm Hg or 0.1 kPa or 0.1 Vol %	+/-1 mm Hg or 0.1 kPa or 0.1 Vol %	---	+/- mm Hg or 0.1 kPa or 0.1 Vol %	Same as Star 90 and Star 55
AA	0.1%	0.1%	---	0.1%	Same as Star 90 and Star 55
N2O	1%	1%	---	1%	Same as Star 90 and Star 55
O2	1%	1%	---	1%	Same as Star 90 and Star 55
Units:					
CO2	mmHg or kPa or Vol %.	mmHg or kPa or Vol %.	---	mmHg or kPa or Vol %.	Same as Star 90 and Star 55
AA/O2/N2O	Vol%	Vol%	---	Vol%	Same as Star 90 and Star 55
Warm-up Phase	ISO accuracy within 45 s, full accuracy within 10 min	ISO accuracy within 45 s, full accuracy within 10 min	---	ISO accuracy within 45 s, full accuracy within 10 min	Same as Star 90 and Star 55

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Pump	Flow controlled dual membrane 70-200+/- 10ml/min or +/- 10% whichever is greatest	Flow controlled dual membrane 70-200+/- 10ml/min or +/- 10% whichever is greatest	---	Flow controlled dual membrane 70-200+/- 10ml/min or +/- 10% whichever is greatest	Same as Star 90 and Star 55
Primary Agent ID Threshold	0.15% (0.4% during ISO accuracy mode)	0.15% (0.4% during ISO accuracy mode)	---	0.15% (0.4% during ISO accuracy mode)	Same as Star 90 and Star 55
Secondary Agent ID Threshold	0.3% (0.5% during ISO accuracy mode) or 5%REL (10% for Isoflurane) of primary agent if primary agent >10%	0.3% (0.5% during ISO accuracy mode) or 5%REL (10% for Isoflurane) of primary agent if primary agent >10%	---	0.3% (0.5% during ISO accuracy mode) or 5%REL (10% for Isoflurane) of primary agent if primary agent >10%	Same as Star 90 and Star 55
Zeroing	Automatically performed by the module. Indicated to the user through a message on the screen. Automatically every 4 hours (in Full accuracy mode) in steady state with room air. Additional zeroing performed during startup.	Automatically performed by the module. Indicated to the user through a message on the screen. Automatically every 4 hours (in Full accuracy mode) in steady state with room air. Additional zeroing performed during startup.	---	Automatically performed by the module. Indicated to the user through a message on the screen. Automatically every 4 hours (in Full accuracy mode) in steady state with room air. Additional zeroing performed during startup.	Same as Star 90 and Star 55
Calibration	Initiated through Power `on` service menu.	Initiated through Power `on` service menu.	---	Initiated through Power `on` service menu.	Same as Star 90 and Star 55
Alarms	Low and high limits adjustable over the complete measurement range	Low and high limits adjustable over the complete measurement range	---	Low and high limits adjustable over the complete measurement range	Same as Star 90 and Star 55

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Delay Time	< 4Sec	< 4Sec	---	< 4Sec	Same as Star 90 and Star 55
Span Calibration Check	Once in a Year	Once in a Year	---	Once in a Year	Same as Star 90 and Star 55
W/f sampling rate	50	50	---		Same as Star 90 and Star 55
No Breath alarm	Within 10-90 seconds when respiration not detected.	Within 10-90 seconds when respiration not detected.	---		Same as Star 90 and Star 55
System outputs	<p>ECG Analog Output Port (For IABP Interface) HDMI : External Slave Display Wi-Fi : Communicating with Central Nursing station (SKANRAY's CNS), Bed To Bed, Network/Wireless Printer Serial Port (1 no) : For AGM55 Connectivity Ethernet (1 no) : Communicating with Central Nursing station (SKANRAY's CNS), Bed To Bed. USB (1 no) : For uploading software into Monitor, Patient Transfer & for trend data download, Bar Code Scanner</p>	<p>ECG Analog Output Port (For IABP Interface) HDMI : External Slave Display Wi-Fi : Communicating with Central Nursing station (SKANRAY's CNS), Bed To Bed, Network/Wireless Printer Serial Port (1 no) : For AGM55 Connectivity Ethernet (1 no) : Communicating with Central Nursing station (SKANRAY's CNS), Bed To Bed. USB (1 no) : For uploading software into Monitor, Patient Transfer & for trend data download, Bar Code Scanner</p>	---		Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Power supply	<p>VOLTAGE : 100 - 240V AC, [50Hz / 60Hz ,+/- 5%] WATTAGE: 100 WATTS FUSE: 3.15A, 250V Fuse in Line & Neutral INDICATOR:</p> <ul style="list-style-type: none"> • Amber LED ON indicates mains on • Green LED ON indicates monitor on • Amber LED OFF and Green LED ON indicates unit is in the battery mode 	<p>VOLTAGE : 100 - 240V AC, [50Hz / 60Hz ,+/- 5%] WATTAGE: 100 WATTS FUSE: 3.15A, 250V Fuse in Line & Neutral INDICATOR:</p> <ul style="list-style-type: none"> • Amber LED ON indicates mains on • Green LED ON indicates monitor on • Amber LED OFF and Green LED ON indicates unit is in the battery mode 	---		Same as Star 90 Safety Approvals attached
BATTERY:					
Internal battery:	Yes	Yes	---	---	Same as Star 90
Type	Single Lithium ion Battery Pack, 14.8V, 4.0 Ah	Single Smart Battery Pack, 10.8V(Nom), Lithium ion	---	---	<p>Different. This difference does not affect safety and efficacy of the device.</p> <p>Also the battery is complies with IEC 62133:2012 and IEC 60601-1</p>
Battery Indication	Main Unit Internal batteries Status will be displayed.	Main Unit Internal batteries Status will be displayed.	---	---	Same as Star 90
External battery provision	No	No	---	---	Same as Star 90
Battery Chemistry	Lithium ion	Lithium ion	---	---	Same as Star 90
Cells Count	8 Cells	6 Cells	---	---	Difference in Voltage

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
					increased cells count. This difference does not affect safety and efficacy of the device. Also the battery is complies with IEC 62133:2012 and IEC 60601-1
Recorder:					
Technology	Thermal recording	Thermal recording	---	Thermal recording	Same as Star 55 and Star 90
No.of waveform channels	2	2	---	2	Same as Star 55 and Star 90
Paper width	58 mm	58 mm	---	58 mm	Same as Star 55 and Star 90
Paper speed	25mm/sec	25mm/sec	---	25mm/sec	Same as Star 55 and Star 90
Other printing options:					
Network Printer Type	PCL 3 / 5e Laser or Inkjet Printer	PCL 3 / 5e Laser or Inkjet Printer	---	---	Same as Star 90
No.of waveform channels	4 (max)	4 (max)	---	---	Same as Star 90
Paper width	Paper Mode (A4) , Paperless Mode (PDF)	Paper Mode (A4) , Paperless Mode (PDF)	---	---	Same as Star 90
Paper speed	NA	NA	---	---	Same as Star 90
OTHER FEATURES / SPECIFICATIONS:					
Operating ambient temperature	0 ° C to 35 ° C	0 ° C to 40 ° C	---	---	Similar as Star 90
Operating Relative humidity	10 – 90%RH (non-condensing)	10 – 90%RH (non-condensing)	---	---	Same as Star 90
Operating Pressure	0 ft – 10,000ft	0 ft – 10,000ft	---	---	Same as Star 90

Title	Subject	Primary Predicate	Secondary Predicate	Tertiary Predicate	Comments
Storage conditions	-10° C to 50° C 0 – 90%RH (non-condensing) Storage pressure: -1,250ft – 15,000ft	-10° C to 50° C 0 – 90%RH (non-condensing) Storage pressure: -1,250ft – 15,000ft	---	---	Same as Star 90
CONNECTORS:	Power: Standard 3-pin IEC power connector with Line, Neutral & Earth with fuse Side panel: Green colour NICOLAY round connector for ECG Yellow colour NICOLAY round connector for SpO2 Metallic Female coupling for NIBP IBP - Red colour NICOLAY round connector CO2 - Filter line Temp – 2 pin connector	Power: Standard 3-pin IEC power connector with Line, Neutral & Earth with fuse Side panel: Green colour NICOLAY round connector for ECG Yellow colour NICOLAY round connector for SpO2 Metallic Female coupling for NIBP IBP - Red colour NICOLAY round connector CO2 - Filter line	---	---	Same as Star 90

Table 2 Substantial Equivalent Comparison

Substantial Equivalence Discussion – with Star 90 (K150512), Star 55 (K080173) and MP50 (K120366)

Similarities between Star 65 & Star 90:

Star 65 is designed and developed with reference to our previous 510K cleared product Star 90. These 2 products are similar in terms of:

- ECG, Respiration, Temperature, IBP, NIBP, SpO2, CO2 and AGM
- Display type
- Alarm systems
- Thermal recorder / printer
- Equipment classification and Applicable standards

Similarities between Star 65 & MP50:

Star 65 is compared with MP50 for:

- Invasive Cardiac Output

Similarities between Star 65 & Star 55:

Star 65 is compared with Star 55 for:

- Keyboard Controls
- Display size

Differences between Star 65 & predicate Devices:

Star 65 is different from Star 90 in terms of:

- Battery

Star 65 is a Single Lithium ion Battery Pack, 14.8V, 4.0 Ah. For the same intended purpose as compared to Predicate device, Star 65 performs equivalent and there is no safety issue due to Single Lithium ion Battery. Hence, these differences between the subject and predicate(s) do not impact safety and effectiveness.

Method of Acceptance – Battery complies with IEC 62133:2012 and IEC 60601-1 standards requirements.

Refer Annexure: **Annexure 12_A IEC 61233:2012 Report, Annexure 17_B Electrical Safety Report 1 and Annexure 12_B IEC 62133 CB Certificate Battery Cells**

We have performed a thorough verification and testing of the differences in checking the performance and the safety and efficacy. So this difference does not affect safety and efficacy of the device.

VII.NON-CLINICAL STUDY

1.1 Electrical, mechanical, environmental safety and performance testing according to the following consensus standards

Consensus Standard number	Standard Description	FDA ID
AAMI / ANSI ES60601-1:2005/(R)2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)	19-4
IEC 60601-1-2 Ed 3: 2007	Medical electrical equipment -Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Following Requirements and tests	19-1
IEC 60601-1-6 Ed 3.1:2013	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	5-89
IEC 60601-1-8 Ed 2.1: 2012	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	5-76
IEC 60601-2-27 Ed 3.0: 2011	Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment	3-126
IEC 80601-2-30 Ed 1.1: 2013	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers	3-123
IEC 60601-2-34 Ed 3.0: 2011	Medical Electrical Equipment - Part 2-34: Particular Requirements For The Basic Safety, Including Essential Performance, Of Invasive Blood Pressure Monitoring Equipment	3-115
IEC 60601-2-49 Ed 2.0: 2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	None
ISO 80601-2-55 First Edition 2011-12-15	Medical Electrical Equipment - Part 2-55: Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitors	1-96
ISO 80601-2-56 First Edition 2009-10-01	Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement	6-232
ISO 80601-2-61 First Edition 2011-04-01	Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment	1-85
IEC 62304 Edition 1.1 2015-06	Medical Device Software - Software Life Cycle Processes	13-79
ISO 14971 Ed 2.0 : 2012	Application of risk management to medical devices	5-40

All test results were satisfactory. Refer EMC Test Summary & Safety Test Report Summary in section 017 “Electromagnetic Compatibility and Electrical Safety” of this submission document.

1.2 Performance testing- Accuracy, Environment cycling, Temperature Rise Test, wireless co-existence were performed according to Design Requirement specification, verification and Validation plans.

“All test results were satisfactory with no deviations from the applicable standards or protocols. Refer summary of performance in section 018 “Performance Testing-Bench” of this submission document for more details”.

The data from the test reports (Annexure 18_A to Annexure 18_I) substantiates the equivalence to the Predicate device, as the specifications of the predicate device and the subject device are similar.

VIII.SOFTWARE VERIFICATION AND VALIDATION TESTING:

Software Verification and Validation Testing Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

IX.CLINICAL STUDY:

Not Applicable, Clinical performance testing was not performed with the subject device to support substantial equivalence.

X. CONCLUSION

Star 65 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.