K123148
P 1/7

K123148
510k Summary Statement (In accordance with 21 CFR 807.92)
Date Prepared: 15 July 2013

Sponsor Information:

PARACE LLC
PO Box 171
Yorktown Heights
NY 10598 USA

NOV 19 2013

Contact Person:	VanDette Carter, PA-C President and Chief Executive Officer
Mailing Address:	2310 Eastchester Road Bronx, NY, 10469
Telephone Number:	914-356-4848
Facsimile Number :	1-718-519-7898
E-mail:	ekoscope@parace.com
Alternate Contact Person:	Fernand A. De Los Reyes, RN, MA Chief Operations Officer
Telephone Number:	845-270-9289
Facsimile Number :	1-718-519-7898
E-mail:	dean.dlr@parace.com
Alternate Contact Person:	Alma L. Carter, RN Chief Compliance Officer
Telephone Number:	877-727-2231
Facsimile Number:	1-718-519-7898
E-mail:	paracecorp@aol.com

Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope with Electrocardiograph Function
Proprietary Name:	PARACE MD® Ekoscope™ Model iS100
Classification Name:	Electronic Stethoscope Class II (Two), 21 CFR 870.1875 Electrocardiograph Class II (Two), 21 CFR

870.2340 Performance Standards: None

Predicate Devices:

3M™ Littmann ® Electronic Stethoscope, Model 4100, K051790
3M™ Littmann® Electronic Stethoscope, Model 3200, K083903
Edan SE-3 Series Electrocardiograph, K091513

Device Description:

The Ekoscope iS100 Device is an electronic stethoscope with 6 leads EKG capability. The electronic microphone can detect sounds between 1.0 Hz to 2KHz from the heart, vessels, lungs and abdomen. The detected sounds are then processed and filtered to reduce ambient

noises and transmitted to a removable headset that contains a built in speaker. The sound may also be amplified or attenuated upon demand. The visceral sounds are processed via three stethoscope modes. The first is the Bell Mode. The Bell mode processes sounds having a frequency range of 20 Hz -500 Hz. Secondly, the Diaphragm mode processes sound within a range of 20 Hz to 700 Hz. The third mode is the Diaphragm Plus mode. The Diaphragm Plus Mode processes mechanical heart sounds between 1KHz to 20 KHz. The acquired visceral sounds, along with EKG data, are stored in 30 seconds increments into the device's 2 Gigabyte SD card for playback, delete or upload via USB to a PC using Microsoft Window® version Operating System. The Ekoscope iS100 is powered by a rechargeable Lithium battery. The battery is rechargeable via a micro USB. It has a built-in penlight accessory with adjustable brightness used to visualize pupil, nasal and oral cavity.

The Ekoscope iS 100 also features 6 electrodes. The electrodes are positioned on the head of the device and body of the device. The strategically placed electrodes are used for the detection of 6 channel electrocardiograph (ECG) signals. The ECG signals are from the chest, hands and left leg, via three designated modes: A, B and C. The acquired data is first stored on the Ekoscope iS 100, and can be uploaded to a compatible PC for printing or sending to another location via the internet.

The sample frequency of ECG signal is 200Hz and the bit resolution is 16bit; Adopts 50/60Hz interference suppression. The sample frequency of heart sounds signal is 48kHz and bit resolution is 16bit. Different digital filters will be used in the Bell Mode, Diaphragm Mode and Diaphragm Plus Mode. The device embedded software, proprietary filter and Digital Signal Processing (DSP) technologies, attenuate ambient noises of sounds within a frequency range of 1.0 Hz to 2.0KHz. The sounds are attenuated while preserving native auscultated sounds of interest.

The display speed of the ECG wave and heart sound wave is different on the device's TFT color screen. The ECG wave has two display speed 12.5mm/s and 25mm/s. The display speed of heart sound is 153mm/s. The display range of the ECG wave is selectable and they are 'x0.5', 'x1' and 'x2'. The display range of heart sound wave is not alterable. ECG display is marked with 'ECG' while the Sound Wave display is marked with 'Sound'.

Indications for Use:

The EKOSCOPE device is intended for medical diagnostic purposes only. It has an electronic stethoscope function with three modes of operation. It also has an electrocardiograph (ECG) function with three modes of operation. The Bell mode processes sounds having a frequency range of 20 Hz -500 Hz. Secondly, the Diaphragm mode processes sound within a range of 20 Hz to 700 Hz. The third mode is the Diaphragm Plus mode. The Diaphragm Plus Mode processes mechanical heart sounds between 1KHz to 20 KHz. The stethoscope function is used for the detection and amplification of sounds from the heart, lungs, arteries, veins and other internal organs during physical assessment. It has a built-in penlight accessory with adjustable brightness used to visualize pupil, nasal and oral cavity.

The ECG mode utilizes one of three modes to detect cardiac electrical activities, specifically from the limb leads, to determine the state of the heart beyond the abilities of a stethoscope. The ECG are detectable by a series of electrodes marked as #1 and #2 as referred in the user manual to user manual to register, record and display the electrical activity of the cardiac cycle in real time. This assessment will allow for the medical professional to then analyze, interpret and diagnose heart rate and rhythm based on recorded limb lead electrocardiogram information. This ECG is not a standard 12-lead ECG and is not suitable for detection of ischemia or infarction. The EKOSCOPE is suitable for adults and pediatrics but not intended for use on infants and in utero. The device is intended for use in hospitals or health care facilities by doctors and trained health care professionals.

Caution: Federal Law restricts this device to sale by or on the order of a licensed health care practitioner.

Effectiveness and Safety Considerations

Combined in functionality with an electronic stethoscope, the Ekoscope^{TM} iS100 is a safe, accurate, and a reliable device for recording ECG data. The Ekoscope^{TM} iS100 device has generally the same technological characteristics and intended use as its predicate device 3M Littmann Model 3200 and 4100 and Edan SE-3 electrocardiograph. The Ekoscope^{TM} iS100 as compared to its predicate devices is more efficient and clinically practical in terms of ease of use and reliability. There are no new questions of safety or effectiveness.

Further, the Ekoscope iS100 is compliant and conforms to international accepted standards on safety and effectiveness. The following are the standards which the Ekoscope iS100 conforms and complies to:

- IEC 60601-1 - Medical equipment/medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 Medical electrical equipment-Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility - Requirements and test
- ANSI/AMMI EC 38:2007 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance of ambulatory electrocardiographic systems
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Comparative Discussion for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that Ekoscope™ Model iS100 is substantially equivalent to the predicate device 3M™ Littmann® Electronic Stethoscope, Model 3200, cleared under K083903 and Littmann® Electronic Stethoscope, Model 4100, cleared under K051790 in terms of intended use, indications for use, composition, physical properties and technological characteristics. In addition, Ekoscope iS100 is substantially equivalent to the predicate device Edan SE-3, cleared under K091513 for its electrocardiograph functions. The device is substantially equivalent to predicate devices in technological characteristics and performance requirements. Comparison of performance features of the Ekoscope iS100 are presented in the two succeeding tables.

Comparison of Performance Features Ekoscope iS100 Stethoscope versus Littmann® Electronic Stethoscope Model 4100 and Littmann® Electronic Stethoscope Model 3200

Performance Features	Littmann Model 4100* (Predicate Device K051790)	Ekoscope iS100 (New Device K123148)
Frequency Response	Bell mode (20-200 HZ) and Diaphragm mode (100-500 Hz)	Bell mode: 20 Hz - 550Hz Diaphragm mode: 20Hz - 700Hz Diaphragm plus mode: 1KHz - 20KHz - Mechanical heart valves are typically between 1.3KHz to 20KHz
Amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification	Up to 30 dB acoustic gain, equivalent to 21.6 times Amplification
Maximum sound level	140 dB SPL Max	87 dB SPL Max (Note that 100dB is the tolerable maximum human threshold for sound)
Power source	Two (2) AAA alkaline batteries	Lithium-ion Battery
Displays heart rate	Yes	Yes
Record and playback sounds	Yes	Yes
Permits data transfer of stored digital signals to and from a Personal Computer	Yes	Yes
Volume Control	8 step volume control	8 step volume control
On/Off Switch Automatic shut-off by Electronics	Yes	Yes

***Approved and cleared under predicate device Littman Model 3200 under K083903**

Comparison of Performance Features Ekoscope iS100 versus Edan SE-3 Electrocardiograph		
Performance Features	Edan SE-3 (Predicate Device K091513)	Ekoscope iS100 (New Device K123148)
Three channel ECG	Yes	Yes
No of Leads	6 to 12 Leads	6 Leads
Power source	Rechargeable Lithium-ion AC/DC power supply	Rechargeable Lithium-ion AC/DC power supply
Intended use	Acquire ECG signals from adult and pediatric patients through body surface ECG electrodes	Acquire ECG signals from adult and pediatric patients through body surface ECG electrodes
Display of ECG signal waveforms	LCD	TFT LCD
Results recording/storage	Thermal printer or USB printer	USB printer and internal 2GB storage
Data transmission	Via PC Ethernet port	Via PC email system
Patient data transfer	USB interface	USB interface
LCD screen	Foldable LCD screen	TFT LCD with touch key interface
ECG Recording Modes	1 ECG Recording Mode	3 ECG Recording Modes: Mode A: 6 Lead (Chest) Mode B: 6 Leads (Hands + Legs) Mode C: 1 Lead (Hands)

Determination of Substantial Equivalence

The Ekoscope™ iS100 complies with voluntary standards as detailed in this pre-market submission. The following quality assurance measures and related measures cited in the attached reports were undertaken and applied to the Ekoscope™ iS100:

- Risk Analysis
- Reliability Test
- Safety Test
- Electromagnetic and Biocompatibility Test
- Performance Test voluntarily against AAMI EC38 Performance
- Product Specification Verification
- Software Verification and Validation

Summary of Clinical Tests and Conclusion:

The Ekoscope™ iS100 which is the subject of this premarket notification submission and bench test as presented in the attachments for this submission, did not require clinical studies to support substantial equivalence.

PARACE LLC's Medical Division considers the electronic stethoscope Ekoscope™ iS100 with electrocardiograph function (ECG) as a product to be as safe, as effective, more compact and efficient and substantially equivalent in performance to its predicate devices. Above all, there are no significant differences that affect the safety or effectiveness of the Ekoscope iS100™ compared to the predicate devices as earlier mentioned.

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

November 19, 2013

Parace LLC
c/o Mr. Vandette Carter
President and Chief Executive Officer
P.O. Box 171
Yorktown Heights, NY 10598 US

Re: K123148
Trade/Device Name: PARACE MD Ekoscope iS100
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: II (two)
Product Code: DQD, DPS
Dated: September 30, 2013
Received: October 8, 2013

Dear Mr. Carter:

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 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123148

Indications for Use

510(k) Number (if known): K123148

Device Name: PARACE MD Ekoscope iS100

Indications For Use:

The EKOSCOPE device is intended for medical diagnostic purposes only. It has an electronic stethoscope function with three modes of operation. It also has an electrocardiograph (ECG) function with three modes of operation. The Belle mode processes sounds having a frequency range of 20Hz to 500Hz. Secondly the Diaphragm mode processes sound within a range of 20 Hz to 700 Hz. The third mode is the Diaphragm plus mode. The Diaphragm plus mode processes mechanical heart sounds between 1KHz to 20KHz. The stethoscope function is used for the detection and amplification of sounds from the heart, lungs, arteries, veins and other internal organs during physical assessment. It has a built-in penlight accessory with adjustable brightness used to visualize pupil, nasal and oral cavity..

The ECG mode utilizes one of three modes to detect cardiac electrical activities, specifically from the limb leads, to determine the state of the heart beyond the abilities of a stethoscope. The ECG are detectable by a series of electrodes marked as #1 and #2 as referred in the user manual to user manual to register, record and display the electrical activity of the cardiac cycle in real time. This assessment will allow for the medical professional to then analyze, interpret and diagnose heart rate and rhythm based on recorded limb lead electrocardiogram information. This ECG is not a standard 12-lead ECG and is not suitable for detection of ischemia or infarction. The EKOSCOPE is suitable for adults and pediatrics but not intended for use on infants and in utero. The device is intended for use in hospitals or healthcare facilities by doctors and trained health care professionals.

Caution: Federal Law restricts this device to sale by or on the order of a licensed health care practitioner.

Prescription Use___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Digitally signed by
Owen P. Faris -S
Date: 2013.11.19
14:38:57 -05'00'