November 14, 2018

snap40 Ltd
Edwin Lindsay
QA/RA Manager
24 Forth Street
Edinburgh, EH1 3LH Gb

Re: K182543
Trade/Device Name: Wearable Device; Cradle; Small Strap, Medium Strap, Large Strap; Multiple Device Charger; Hospital Starter Package
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, DQA, BZQ, FLL, DRG
Dated: September 17, 2018
Received: September 20, 2018

Dear Edwin Lindsay:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Arielle Drummond -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

Indications for Use

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

510(k) Number *(if known)*
K182543

Device Name
snap40 System

Indications for Use *(Describe)*

snap40 is intended for reusable bedside, mobile and central multi-parameter, continuous and intermittent physiologic patient monitoring of adult patients in environments where patient care is provided by trained healthcare professionals.

snap40 is intended to provide visual and audible physiologic multi-parameter alarms.

snap40 is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated.

snap40 continuously monitors the following parameters in adults:

- Pulse rate
- Oxygen saturation
- Temperature
- Movement

snap40 is intended for intermittent or spot-check monitoring of respiration rate.

snap40 is not intended for use in high-acuity environments, such as ICU or operating rooms or for use in the home

snap40 is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. snap40 is not a substitute for an ECG monitor.

snap40 is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

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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snap40 Ltd.
Traditional 510(k)
For snap40 system

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

snap40 Ltd

Submitter's Address:

24 Forth Street,
Edinburgh
EH1 3LH
United Kingdom

Telephone: +44 (0) 131 560 1137

Establishment Registration Number:

Still to be established

Contact Person:

Edwin Lindsay

Telephone +44 (0) 7917134922

Date Prepared:

4th September 2018

Below summaries the Device Classification Information regarding the snap40 System:

Primary Product Code:

Regulation Number	Device	Device Class	Product Code	Classification Panel
870.2300	System, Network and Communication, Physiological Monitors	Class 2	MSX	Cardiovascular

Secondary Product Codes:

Regulation Number	Device	Device Class	Product Code	Classification Panel
880.2910	Thermometer, Electronic, Clinical	Class 2	FLL	General Hospital
870.2700	Oximeter	Class 2	DQA	Cardiovascular
868.2375	Monitor, Breathing Frequency	Class 2	BZQ	Anesthesiology
870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency	Class 2	DRG	Cardiovascular

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Traditional 510(k)
For snap40 system

Device Trade Name:

snap40 system

Device Common Name:

snap40 system

Intended/ Indications Use:

snap40 is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in environments where patient care is provided by trained healthcare professionals.

snap40 is intended to provide visual and audible physiologic multi-parameter alarms.

snap40 is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated.

snap40 is intended for continuous monitoring of the following parameters in adults:

- Pulse rate
- Oxygen saturation
- Temperature
- Movement

snap40 is intended for intermittent or spot-check monitoring of respiration rate in adults.

snap40 is not intended for use in high-acuity environments, such as ICU or operating rooms or for use in the home

snap40 is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. snap40 is not a substitute for an ECG monitor.

snap40 is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

Summary of Substantial Equivalence:

The following predicate devices have been chosen that the snap40 system can claim equivalence with and these are detailed below

General Comparison

General Information					
Property	***Proposed Device* snap40**	***Primary Predicate* IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Common Name	**System, Network and Communication, Physiological Monitors**	**Monitor, Physiological, Patient (With Arrhytmia Detection or Alarms)**	**Monitor, Physiological, Patient (With Arrhyhmia Detection or Alarms)**	**Monitor, Breathing Frequency**	**Display, Cathode-Ray Tube**
Device Manufacturer	**snap40 Ltd**	**Draeger**	**Draeger**	**Philips**	**Philips**
Device Classification	**II**	**II**	**II**	**II**	**II**
Primary Product Code	**MSX**	**MHX**	**MHX**	**BZQ**	**DXJ**
Secondary Product Code	**FLL DQA BZQ DRG**	**MSX, DRT, DQA, BZQ, FLL, DSK, FLS, MLD, DXN, CCK**	**-**	**DRG MSX**	**DQK NSX OUG**
510k Numbers	**N/A**	**K113798**	**K151860**	**K132320**	**K161767**
Target Population	**Adult**	**Adult, Paediatric and Neonatal**	**Adult, Paediatric and Neonatal**	**Adult**	**N/A**
Environment	**Hospital**	**Hospital**	**Hospital**	**Hospital**	**Hospital**
Intended Use/ Indication for Use	**snap40 is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in environments where patient care is provided by trained**	**The IACS is intended for multi-parameter, physiologic patient monitoring of adult, pediatric and neonatal patients in environments where patient care is provided by**	**The Infinity CentralStation (ICS) is intended for use by trained healthcare professionals for the purpose of centralized monitoring of adult, pediatric and neonatal patient data within the**	**The IntelliVue CL Respiration Pod is indicated for use by healthcare professionals whenever there is a need for intermittent or spot-check acquisition**	**The IntelliVue GuardianSoftware is indicated for use by healthcare providers whenever there is a need for the generation of a patient record.** **The IntelliVue**

General Information					
Property	***Proposed Device* snap40**	***Primary Predicate* IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
	healthcare professionals. **snap40 is intended to provide visual and audible physiologic multi-parameter alarms.** **snap40 is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated.** **snap40 is intended for continuous monitoring of the following parameters in adults:** **Pulse rate** **Oxygen saturation** **Temperature** **Movement** **snap40 is intended for intermittent or spot-check monitoring of**	**trained healthcare professionals.** **The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The transfer of this data is accomplished by the Infinity network.** **The Infinity M540 is intended for the monitoring of multi-parameter, physiological patient information obtained from connected hardware in environments where patient care is provided by trained healthcare**	**hospital or clinical environment. Centralized monitoring involves the display and management of data from networked patient monitors including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation. Infinity CentralStation with Rest ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and pediatric patients when connected to a monitor with diagnostic 12-Lead ECG monitoring enabled.**	**and monitoring of physiological patient parameters respiration rate and pulse rate wirelessly in specific hospital areas. The IntelliVue CL Respiration Pod is mainly indicated for use in general medical and surgery wards and in waiting areas of emergency rooms.** **It is not indicated for use in hospital areas in which continuous patient monitoring is needed, such as intensive care units or operating rooms.** **The intended use of the IntelliVue CL**	**GuardianSoftware is intended for use in the collection, storage and management of data from Philips specified Measurements and Philips Patient Monitors that are connected through networks.**

General Information					
Property	***Proposed Device* snap40**	***Primary Predicate* IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
	respiration rate in adults. **snap40 is not intended for use in high-acuity environments, such as ICU or operating rooms or for use in the home** **snap40 is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. snap40 is not a substitute for an ECG monitor.** **snap40 is not intended for SpO2 monitoring in conditions of high motion or low perfusion.**	**professional. The M540 is intended to monitor one patient at a time.** **The M540 monitors the following parameters:** **· Heart rate** **· Arrhythmia (adult and pediatric only)** **· 12-lead analysis** **· ST segment analysis including TruST® (adult and pediatric only)** **· 12-lead ST segment analysis (adult and pediatric only)** **· Apnea** **· Respiration rate** **· Invasive pressure** **· Non-invasive pressure** **· Temperature** **· Cardiac output (only available when the M540 is docked in an**		**Respiration Pod when used together with a patient monitor is for intermittent or spot-check monitoring and recording of, and to generate alarms for, respiration rate and pulse rate of adult patients.** **The IntelliVue CL Respiration Pod is also intended for acquisition of respiration rate and pulse rate data of adult patients for a clinical information management system.** **The Intellivue CL Respiration Pod is intended for use by healthcare professionals. It is not**	

General Information					
Property	***Proposed Device* snap40**	***Primary Predicate* IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
		IACS configuration) **· Arterial oxygen saturation (SpO 2)** **· Pulse rate** **· Perfusion Index (P1)** **· Total hemoglobin (SpHb) - adult and pediatric only** **· Total oxygen content (SpCO) - adult and pediatric only** **· Methemoglobin saturation (SpMet)** **· Pleth variability index (PVI)** **· Mainstream etCO2**		**intended for home use. It is not a therapeutic device.** **The IntelliVue CL Respiration Pod is not intended for use on patients with extremely high values for respiration rate (above 60 rpm).** **The IntelliVue CL Respiration Pod is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g. very fast atrial fibrillation or ventricular tachycardia (rapid irregular pulse rate) . For**	

General Information					
Property	***Proposed Device* snap40**	***Primary Predicate* IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
				monitoring of these patients, a device for continuous ECG monitoring is necessary. The IntelliVue CL Respiration Pod is not a substitute for an ECG monitor. **Warning: Do not use the CL Respiration Pod on patients with rapid, irregular heart rates greater than 110 bpm. Use under these conditions has not been clinically validated.**	

System Information					
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Parameters Monitored	**Pulse Rate** **Oxygen Saturation** **Respiration Rate** **Temperature** **Movement**	**Heart rate** **Arrhythmia (adult and pediatric only)** **12-lead analysis** **ST segment analysis including TruST® (adult and pediatric only)** **12-lead ST segment analysis (adult and pediatric only)** **Apnea** **Respiration rate** **Invasive pressure** **Non-invasive pressure** **Temperature** **Cardiac output (only available when the M540 is docked in an IACS configuration)** **Arterial oxygen saturation (SpO 2)** **Pulse rate** **Perfusion Index (P1)** **Total hemoglobin (SpHb) - adult and pediatric only** **Total oxygen content (SpCO) - adult and pediatric only** **Methemoglobin saturation (SpMet)** **Pleth variability index (PVI)** **Mainstream etCO2**	**N/A**	**Respiration Rate** **Pulse Rate**	**N/A**
Alarms	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Energy Source	**Battery**	**Primarily Mains + Battery Backup & For Patient Transport**	**Mains**	**Battery**	**Mains**
Battery Type	**Lithium Ion**	**Lithium Ion**	**N/A**	**Lithium Ion**	**N/A**
Battery Operating Time	**36 Hours**	**3 Hours**	**N/A**	**24 Hours**	**N/A**
Battery Indicator	**Via User Interface (Central/Bedside/Mobile)**	**Via User Interface (Bedside)**	**N/A**	**Via**	**On Device**
Central Monitoring	**Yes**	**No**	**Yes**	**N/A**	**Yes**
User Interface Displayable at Bedside	**Yes**	**Yes**	**No**	**N/A**	**No**
Interfaces	**Central/Bedside/ Mobile**	**Bedside**	**Central**	**Via IntelliVue Guardian Software**	**Central /Mobile**
Displayed Information on Interface	**Vital Sign Parameters + Alarms**	**Vital Sign Parameters + Alarms**	**Vital Sign Parameters + Alarms**	**Vital Sign Parameters + Alarms**	**Vital Sign Parameters + Alarms**

snap40 Ltd.
Traditional 510(k)
For snap40 system

System Information					
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Labelling	**Comply with FDA Requirement**	**Comply with FDA Requirement**	**Comply with FDA Requirement**	**Comply with FDA Requirement**	**Comply with FDA Requirement**
Network Communication	**IEEE 802.11 WiFi**	**IEEE 802.11 WiFi**	**LAN**	**IEEE 802.15.4**	**LAN**
Data Update Period	**30 seconds**	**<10 seconds**	**N/A**	**Up to 30 Seconds**	**N/A**

Technical Information for Pulse Rate						
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**		**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Module	**snap40 Module**	**Nellcor OxiMax**	**Massimo Rainbow SET**	**N/A**	**Philips Module**	**N/A**
Site of Sensing	**Upper Arm**	**Finger**	**Finger**	**N/A**	**Left Costal Arch**	**N/A**
Range	**30bpm to 240bpm**	**20bpm to 250 bpm**	**25bpm to 240 bpm**	**N/A**	**30 to 220 bpm**	**N/A**
Resolution	**1bpm**	**1bpm**	**1bpm**	**N/A**	**1bpm**	**N/A**
Accuracy	**± 3bpm**	**± 3bpm**	**±3bpm**	**N/A**	**±3% or ± 1bpm (whichever is greater)**	**N/A**
Applicable Standards	**Complies to ISO80601-2-61**	**Complies to ISO80601-2-61**	**Complies to ISO80601-2-61**	**N/A**	**Complies to ISO80601-2-61**	**N/A**

Technical Information for Oxygen Saturation						
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**		**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Module	**In-Built SpO2**	**Nellcor OxiMax**	**Massimo Rainbow SET**	**N/A**	**N/A**	**N/A**
Site of SpO2 Monitoring	**Upper Arm**	**Finger**	**Finger**	**N/A**	**N/A**	**N/A**
Measuring Range	**0% to 100%**	**0% to 100%**	**0% to 100%**	**N/A**	**N/A**	**N/A**
Range	**70-100%**	**70% to 100%**	**70% to 100%**	**N/A**	**N/A**	**N/A**
Resolution	**1%**	**1%**	**1%**	**N/A**	**N/A**	**N/A**
Accuracy	**± 2 Digits**	**± 2 Digits**	**± 2 Digits**	**N/A**	**N/A**	**N/A**
Applicable Standards	**Complies to ISO80601-2-61**	**Complies to ISO80601-2-61**	**Complies to ISO80601-2-61**	**N/A**	**N/A**	**N/A**

Technical Information for Respiratory Rate					
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Method	**Chest Movement Detection**	**Impedance Pneumography**	**N/A**	**Chest Movement Detection**	**N/A**
Site of Respiratory Rate Monitoring	**Upper Arm**	**Chest**	**N/A**	**Left Costal Arch**	**N/A**
Range	**6 – 60 breaths per minute**	**0 – 155 breaths per minute**	**N/A**	**5 – 60 breaths per minute**	**N/A**
Resolution	**1 breath per minute**	**1 breath per minute**	**N/A**	**1 breath per minute**	**N/A**

Technical Information for Movement					
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Method	**Accelerometer & Gyroscope**	**N/A**	**N/A**	**Accelerometer & Gyroscope**	**N/A**
Site of Movement Monitoring	**Upper Arm**	**N/A**	**N/A**	**Left Costal Arch**	**N/A**
Classification	**10 Levels – 1 (Very Low Activity) to 10 (Very High Activity)**	**N/A**	**N/A**	**10 Levels - 1 (Very Low Activity) to 10 (Very High Activity)**	**N/A**

Technical Information for Skin Temperature					
Property	***Proposed Device*** **snap40**	***Primary Predicate*** **IACS**	**Infinity Central Station**	**IntelliVue CL Respiration Pod**	**IntelliVue Guardian Software**
Method	**Skln Temperature via In-Built Thermistor**	**Skin Temperature via Thermistor in Accessory**	**N/A**	**N/A**	**N/A**
Site of Temperature Monitoring	**Upper Arm**	**Selected by Physician (Can be Upper Arm)**	**N/A**	**N/A**	**N/A**
Range	**0°C to 50°C**	**0°C to 50°C**	**N/A**	**N/A**	**N/A**
Resolution	**0.1°C**	**0.1°C**	**N/A**	**N/A**	**N/A**
Accuracy	**±0.1°C**	**±0.1°C**	**N/A**	**N/A**	**N/A**
Applicable Standard	**Complies to ISO80601-2-56**	**Complies to ISO80601-2-56**	**N/A**	**N/A**	**N/A**

Any technical differences have been justified, both scientifically and using performance testing. These do not affect the safety or effectiveness of the proposed device.

Device Description:

snap40 consists of a single monitoring device worn on the upper arm, a software platform (containing an alarming system) and a user interface to allow presentation of vital signs data both on mobile devices and a central station.

snap40 is intended to continuously monitor adult patient vital signs in non-critical areas of the hospital, mainly general medical/surgical units, across pulse rate (PR), oxygen saturation (SpO2), temperature (TEMP) and movement (MOVEMENT). snap40 is intended for intermittent or spot-checking monitoring of respiration rate (RESP).

Technological Characteristics:

A comparative review of the snap40 system with the predicate device found that the technology, mode of operation, and general principles for treatment with this device were substantially equivalent to the predicate device.

Non-Clinical Tests (Performance/Physical Data):

The snap40 system was evaluated for its safety and effectiveness based on the following testing:

Test Name	Test Description	Results
Electrical Safety	The snap40 System was tested to confirm that it met the applicable standards for electrical safety (IEC 60601-1)	Passed
EMC	The snap40 System was tested to confirm that it met the applicable standards for electromagnetic compatibility (EMC) (IEC 60601-1-2)	Passed
Environment Testing	The snap40 System was tested to confirm the storage and operating temperature ranges.	Passed
Alarm Testing	The snap40 System was tested to confirm that it met the applicable standards for basic safety and essential performance for alarm systems (IEC 60601-1-8) Alarm Function Verification Tests for each parameter function were performed.	Passed
Pulse Rate Testing Validation of the accuracy of pulse rate monitoring	The snap40 System was tested to confirm the accuracy of pulse rate monitoring of the system in accordance with ISO 80601-2-61 and the FDA Pulse Oximeters – Premarket Notification Submissions: Guidance for Industry and FDA Staff. 2007	Passed

Test Name	Test Description	Results
Battery Testing	snap40 Wearable Device Battery Life testing was performed to determine the battery life of the Wearable Device while operating in various modes as well as time to fully charge.	Passed
Usability Testing	snap40 System was assessed with regards to usability for compliance with IEC 62366 - Medical devices - Application of usability engineering to medical devices	Passed
Device Ship/Transport Testing	Ensure device, enclosed in the selected shipping container, meets ASTM D4169 specifications.	Passed
Biocompatibility Testing	Testing and analysis of the snap40 System has demonstrated compliance to ISO 10993-1: Biological evaluation of medical devices – Guidance	Passed
SpO2 Testing Validation of the accuracy of SpO2 monitoring	Ensure the accuracy and communication of the SpO2 functions within the snap40 system as per ISO80601-2-61 and the FDA SpO2 guidance; Pulse Oximeters-Premarket Notification Submissions Guidance for Industry and Food and Drug Staff, March 4, 2013	Passed
Respiratory Rate Testing	Ensure accuracy of snap40 respiration rate in comparison to respiration rate measured via end-tidal CO2 in a variety of postures	Passed
Temperature Measurement Accuracy	snap40 System was tested to confirm the Temperature Measurement Accuracy of the system in compliance with ISO 80601-2-56	Passed
Wireless Radio Communication (Wireless Coexistence Testing)	snap40 System was tested to ensure device can communicate via wireless radio in its intended environment in compliance with FDA Radio Frequency Wireless Technology in Medical Devices Guidance, issued August 2013	Passed
System Verification and Validation Testing	The system verification and validation testing was performed to verify the software and firmware of the snap40 System.	Passed

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 "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator or a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Animal Studies

No animal studies were conducted as part of submission to prove substantial equivalence.

Clinical Studies

Clinical studies were conducted to assess accuracy of both SpO2 and respiration rate.

To assess oxygen saturation, controlled desaturation studies were conducted in compliance with IEC80601-2-61 across 12 participants. This testing demonstrated accuracy of +/- 2 digits across the range of 70-100%. This testing was not conducted in the presence of motion or low perfusion.

To assess respiration rate, snap40 was compared to respiration rate measured by end-tidal CO2. This was conducted on 37 participants in a variety of postures. This testing demonstrated accuracy of +/- 1 respirations per minute across a range of 6rpm to 60rpm.

Safety and Effectiveness/Conclusion:

Based on the information presented in these 510(k) premarket notifications the snap40 system is considered substantially equivalent. The snap40 system is substantially equivalent to the currently marketed predicate devices.

Based on testing and comparison with the predicate devices, the snap40 system indicated no adverse indications or results. It is our determination that the snap40 system performs within its design specifications and is substantially equivalent to the predicate device.