January 23, 2020

Seca GmbH & Co. Kg
℅ Oliver Eikenberg
Senior Consultant QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K192092
Trade/Device Name: seca mVSA 535
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, FLL
Dated: December 19, 2019
Received: December 23, 2019

Dear Oliver Eikenberg:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K192092

Device Name
seca mVSA 535

Indications for Use *(Describe)*

The medical Vital Signs Analyzer seca mVSA 535 is a Spot-Check device used for non-invasive, discontinuous measurement and display of NIBP (blood pressure), SpO2 (oxygen saturation of arterial hemoglobin), TEMP (body temperature) and PR (pulse rate).

The vital signs monitor model seca mVSA 535 is mainly used in inpatient facilities (hospitals, medical practices and care facilities) in accordance with national regulations and is intended to be used on adult and pediatric individuals (3 years of age or older).

The seca mVSA 535 can be used in conjunction with an optional PC software accessory for data management, calculations and display of information.

If used in conjunction with seca medical weight and height measurement devices the seca mVSA 535 can receive and display weight and height values.

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

seca mVSA 535

K192092

1. Submission Sponsor

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2. Submission Correspondent

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Title: Senior Consultant, Quality & Regulatory Affairs

3. Date Prepared

22/01/2020

4. Device Identification

Trade/Proprietary Name(s): seca mVSA 535

Common/Usual Name:	Vital Signs Analyzer
Classification Name:	Noninvasive blood pressure measurement system.
Regulation number:	21 CFR 870.1130 Non-invasive Blood Pressure Measurement System 21 CFR 870.2700 Oximeter 21 CFR 880.2910 Clinical electronic thermometer
Product Code:	DXN, DQA, FLL
Device Class:	Class II Classification
Panel:	Cardiovascular

5. Legally Marketed Predicate Device

SunTech CT40 Spot-check Vital Signs Device (Model 260), (Trade names CT40, Model 260, CT40 Spot-check Vital Signs Device), K160439, manufactured by SunTech Medical, NC, USA.

The predicate device has not been subject to a design related recall.

6. Indication for Use Statement

The medical Vital Signs Analyzer **seca mVSA 535** is a Spot-Check device used for non-invasive, discontinuous measurement and display of NIBP (blood pressure), SpO_2 (oxygen saturation of arterial hemoglobin), TEMP (body temperature) and PR (pulse rate).

The vital signs monitor model **seca mVSA 535** is mainly used in inpatient facilities (hospitals, medical practices and care facilities) in accordance with national regulations and is intended to be used on adult and pediatric individuals (3 years of age or older).

The **seca mVSA 535** can be used in conjunction with an optional PC software accessory for data management, calculations and display of information.

If used in conjunction with seca medical weight and height measurement devices the **seca mVSA 535** can receive and display weight and height values.

7. Device Description

The **seca mVSA 535** is a portable, non-invasive, reusable microprocessor-controlled, AC or DC-powered Vital Signs Analyzer providing discontinuous Spot-Check measurements of vital sign parameters of a patient (adult and pediatric individuals >3 years) in a clinical settings (hospitals, medical practices and care facilities). The vital sign data help clinicians to manage and monitor health conditions of patients.

The **seca mVSA 535** is used by a health care provider (HCP) in a clinical setting, only. During the start the **seca mVSA 535** performs a self-check. The user is not required to perform any special maintenance and/or calibration activities. Users do not require any special training other than the provided instructions for use.

The **seca mVSA 535** does not include alarms or arrhythmia detection.

The following vital signs are measured:

- Blood pressure (NIBP),
- Oxygen saturation of arterial hemoglobin (SpO_2)
- Body temperature (TEMP) (oral/axillary/rectal)
- Pulse rate (PR) – this parameter is not measured but determined while measuring blood pressure or SpO_2

8. Substantial Equivalence Discussion

The following table compares the **seca mVSA 535** to the predicate device with respect to indications for use, principles of operation, technological characteristics and performance specifications. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics for seca mVSA 535 versus CT40 Spot-check Vital Signs Device (Model 260)

	Subject Device	**Predicate Device**	**Device Comparison**
Manufacturer	**seca gmbh & co. kg (GERMANY)**	**SunTech Medical (USA)**	
Trade Name	**medical Vital Sings Analyzer 535 (seca mVSA 535)**	**CT40 Spot-check Vital Signs Device (Model 260)**	
510(k) Number	Unknown	K160439	*NA*
Product Code	DXN, DQA, FLL		***Same***
Regulation Number Regulation Name	21 CFR 870.1130 Non-invasive Blood Pressure Measurement System 21 CFR 870.2700 Oximeter 21 CFR 870.2910 Clinical electronic thermometer		***Same***
Regulation Panel	Cardiovascular		***Same***
Prescription Use	Yes	Yes	***Same***
Indications for Use	The medical Vital Signs Analyzer seca mVSA 535 is a Spot-Check device used for non-invasive, discontinuous measurement and display of NIBP (blood pressure), SpO2 (oxygen saturation of arterial hemoglobin), TEMP (body temperature) and PR (pulse rate). The vital signs monitor model seca mVSA 535 is mainly used in inpatient facilities (hospitals, medical practices and care facilities) in accordance with national regulations and is intended to be used on adult and pediatric individuals (3 years of age or older). The seca mVSA 535 can be used in conjunction with an optional PC software accessory for data management, calculations and display of information. If used in conjunction with seca medical weight and height measurement devices the seca mVSA 535 can receive and display weight and height values.	The SunTech CT40 (Model 260) is a non-invasive oscillometric spot check vital signs device. The CT40 is capable of measuring and displaying brachial systolic and diastolic blood pressure, heart rate, percent oxygenated hemoglobin (SpO2) and body temperature on children 3 years of age to adults. This device is intended for use by a qualified clinician when it is necessary to take one or more vital signs measurements on a patient. The CT40 is only for measurement, recording, and display. It makes no specific diagnoses.	***Similar***
Target Population	Adult and pediatric patients over the age of 3 years	Adult and pediatric patients over the age of 3 years	***Same***
Primary Location of Use	Physician's office, clinic, research center (under supervision of physician)	Physician's office, clinic, research center (under supervision of physician)	***Same***
Device variants	Pre-defined configurations in production: - NIBP + SpO2 - NIBP + TEMP - NIBP + SpO2 + TEMP	configurations can be retrofit (optional): - NIBP only - NIBP + SpO2 - NIBP + TEMP - NIBP + SpO2 + TEMP	***Similar***
Physiological parameters (measured, calculated)	Non-invasive Blood pressure (NIBP) Temperature (TEMP) Oxygen saturation of arterial hemoglobin (SpO_2) Pulse rate (calculated via NIBP or SpO_2)	Non-invasive Blood pressure (NIBP) Temperature (TEMP) Oxygen saturation of arterial hemoglobin (SpO_2) Heart Rate (calculated via NIBP or SpO_2)	***Same***

Table 5A – Comparison of Characteristics for seca mVSA 535 versus CT40 Spot-check Vital Signs Device (Model 260)

	Subject Device	**Predicate Device**	**Device Comparison**
Manufacturer	**seca gmbh & co. kg (GERMANY)**	**SunTech Medical (USA)**	
Trade Name	**medical Vital Sings Analyzer 535 (seca mVSA 535)**	**CT40 Spot-check Vital Signs Device (Model 260)**	
Non invasive Blood pressure (NIBP)			
Mode of Operation	Oscillometric (deflation/inflation)	Oscillometric (deflation, auscultatory)	***Similar***
Measurement mode	Single automatic, repetitive automatic (3 consecutive measurements)	Single automatic, repetitive automatic (5 consecutive measurements)	***Similar***
Measurement type	Systolic Pressure (SYS) Diastolic Pressure	Systolic Pressure (SYS) Diastolic Pressure (DIA)	***Same***
Max. cuff pressure	300 mmHg	300 mmHg	***Same***
Measurement range	Systolic (Adult/Ped.): 25-280 mmHg Diastolic (Adult/Ped.): 10-220 mmHg	Systolic (Adult): 40-260 mmHg Systolic (Pediatric): 40-230mmHg Diastolic (Adult): 25-200 mmHg Diastolic (Pediatric): 20-160 mmHg	***Similar,*** *seca does not have a neonatal mode, but instead has a broader measurement range. Both devices cover ranges around the normal blood range 120/80 mmHg*
Oxygen saturation of arterial hemoglobin (SpO_2)			
Mode of Operation	Pulse Oximetry	Pulse Oximetry	***Same***
Measurement range	70-100 %	70-100 %	***Same***
Body temperature (TEMP)			
Modes of Operation for measuring sites (different modules)	Direct, predictive for oral, axillary, rectal measurement temperature (COVIDIEN FILAC 3000)	Direct, predictive for oral, axillary, rectal measurement	***Same***
Power Supply **Battery type** **Nominal Voltage/Capacity**	100-240 VAC / 50-60 Hz Lithium Ion 11.25 V / 2950 mAh	100-240 VAC, 50-60Hz Lithium Ion 7.2 V / 6600 mAh	***Similar***
Alarm functionality	No built-in Alarm functionality (spot check use only).	No built-in Alarm functionality (spot check use only).	***Same***
Operation	Graphical User Interface with touch control	LCD-Display with button control	***Similar***
Software	Software program is built into the device used to process, store and display information	Software program is built into the device used to process, store and display information	***Same***
EMC/EC testing	IEC 60601-1, IEC 60601-1-2 IEC 60601-1-6 IEC 80601-2-30, ISO 80601-2-56 ISO 80601-2-61	IEC 60601-1, IEC 60601-1-2 IEC 60601-1-6 IEC 80601-2-30, ISO 80601-2-56 ISO 80601-2-61	***Same***
Biocompatibility	ISO 10993 series	ISO 10993 series	***Same***

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of **seca mVSA 535** and in showing substantial equivalence to the predicate device, seca gmbh & co. kg completed the following tests, where the **seca mVSA 535** meets all the requirements for overall design, EMC testing and biocompatibility results confirming that the design output meets the design inputs and specifications for the device.

The seca gmbh & co. kg passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility evaluation and biocompatibility testing of **seca mVSA 535** for patient-contacting materials including chemical characterization, cytotoxicity, sensitization and irritation reactivity, per ISO 10993-1, 5, 10; PASSED all testing
- Electrical safety testing per ANSI/AAMI ES60601-1, IEC 60601-1-6: PASSED required testing
- Electromagnetic Compatibility testing per IEC 60601-1-2: PASSED required testing
- Usability engineering testing per IEC 62366: PASSED required testing
- Software verification and validation testing has been completed on a functional level for a Moderate Level of Concern software including system compatibility testing, risk analysis per IEC 62304/FDA Guidance: PASSED required testing
- Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers per ISO 80601-2-30, PASSED required testing
- Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement per ISO 80601-2-56, PASSED required testing
- Particular requirements for basic safety and essential performance of pulse oximeter equipment per ISO 80601-2-61, PASSED required testing
- Risk Management per ISO 14971 and EN ISO 14971; all requirements were met and risks reduced as far as possible.

10. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the minor differences between the **seca mVSA 535** and the Predicate Device do not raise any new questions regarding its safety and effectiveness. Technological product characteristics, performance testing and compliance with voluntary standards, demonstrate that the **seca mVSA 535** device is substantially equivalent to the predicate device in terms of design, components, materials, principals of operation, performance characteristics, and intended use.