December 28, 2018

Corscience GmbH & Co.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K183369
Trade/Device Name: COR12 ECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 2, 2018
Received: December 4, 2018

Dear Mark Job:

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)*

K183369

Device Name

COR12 ECG

Indications for Use *(Describe)*

The COR12 ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper. The COR12 ECG can be used for applications in patients age 4 years and older and a weight of 20 kg or higher. The COR12 ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital).

Type of Use *(Select one or both, as applicable)*

X 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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Proprietary or Trade Name: COR12 ECG

Common/Usual Name: Electrocardiograph

Classification Name:
21 CFR 870.2340
DPS – Electrocardiograph
Class II

Predicate Devices: K150810 – CareFusion - Vyntus ECG

Device Description
The COR12 ECG is intended for the recording of 12-lead ECG data of a patient by trained staff, e.g., nurse, doctor's assistant or the doctor. This can be performed as a resting or a stress ECG.

It transmits the ECG data in a specified format by Bluetooth® transmission to a customer-defined host software running with its own display, which is not part of the COR12. There is no display of ECG waveforms on the COR12.

Limitation:
- It is not suitable to be used with High Frequency surgery devices.
- Not intended for intracranial use.
- Not intended for use in an EMS environment (Emergency Medical Services Environment).
- Not intended for use in home healthcare environments.

It has a single power-ON button to start data collecting and automatically turns off after 10 minutes of inactivity.

Indications for Use
The COR12 ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper. The COR12 ECG can be used for applications in patients age 4 years and older and a weight of 20 kg or higher. The COR12 ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital).

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Comparison to Predicate

We present in **Tables 5.1 – 5.2** a comparison of the subject device compared to the predicate.

Table 5.1 – Indications and Classification Comparison of Subject and Predicates

	Subject Device	K150810	Comment
Product Name	COR12 ECG	Vyntus/Sentry Suite Product Line Vyntus ECG	
Product Code	DPS	DPS and BZC	DPS is a secondary product code and CFR in the predicate
CFR	870.2340	868.1880	
Classification Name	Electrocardiograph	Pulmonary Function Data Calculator	
Indications for Use	The COR12 ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper.	The Vyntus ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper.	Identical
Data collection only	Yes	Yes	
Test conditions	The COR12 ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions.	The Vyntus ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions.	Identical
Population	The patient population for this device is age 4 years and older and a weight of 20 kg or higher.	The patient population for this device is age 4 years and older and a weight of 20 kg or higher.	Identical
Environments of Use	The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital).	The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital).	Identical

Table 5.2 – Comparison of Technical Specifications

	Subject Device – COR12 ECG	**Primary Predicate – Vyntus ECG – K150810**
Feature	**Value**	
Records ECG only	Yes	Yes
Data output	Recorded and displayed on screen or printed	Recorded and displayed on screen or printed
Records	Under resting and stress conditions	Under resting and stress conditions
Dimensions W x H x D	8.0 x 9.3 x 2.1 cm (3.3 x 3.7 x 0.8 in)	8.0 x 9.3 x 2.1 cm (3.3 x 3.7 x 0.8 in)
Weight (without battery)	200 g (0.4 lbs)	200 g (0.4 lbs)
12-channel Surface ECG Recording	Yes	Yes
Electrodes	Standard ECG electrodes	Standard ECG electrodes
Connection of the electrodes	4 mm snap, gilded	4 mm snap, gilded
Technology of ECG signal	Impedance measurement	Impedance measurement
Accuracy of the ECG signal	1,94µV/bit resolution (at sampling rate of 500 Hz)	1,94µV/bit resolution (at sampling rate of 500 Hz)
Filter	Bandpass 0.05 Hz – 150 Hz No line filter (50 Hz / 60 Hz)	Bandpass 0.05 Hz – 150 Hz No line filter (50 Hz / 60 Hz)
Pacemaker detection	4000 Hz	4000 Hz
Temperature range operation	T = 10 – 37 °C	T = 10 – 37 °C
Ambient pressure range operation	700 to 1060 hPa (525 to 795 mmHg)	700 to 1060 hPa (525 to 795 mmHg)
Humidity (operation, storage, transport)	5 – 95% RH (not condensing)	5 – 95% RH (not condensing)
Power supply	1x AA Alkaline (professional or rechargeable) battery or rechargeable NiMH battery	1x AA Alkaline (professional or rechargeable) battery or rechargeable NiMH battery
Runtime	> 5h with AA battery > 8h with rechargeable NiMH battery (2850 mAh)	> 5h with AA battery > 8h with rechargeable NiMH battery (2850 mAh)
Current consumption at 1.5 V - Operation / Idle	230 mA / 185 mA	230 mA / 185 mA
Classification according to 60601-1 - Protection type against electric shock - Protection level against electric shock	Device with internal power supply Type CF	Device with internal power supply Type CF

Recovery Time after defibrillation	< 8 seconds	< 8 seconds
Electromagnetic compatibility (EMC) according to 60601-1-2 and 60601-2-25 - Emission - Immunity	CISPR 11 Class B IEC 61000-4 parts 2, 3, 6, 8	CISPR 11 Class B IEC 61000-4 parts 2, 3, 6, 8
Data transmission	Bluetooth 2.1+EDR Protocol: SPP.	Bluetooth 2.1+EDR Protocol: SPP.

Discussion of the Comparison and Differences

As presented in **Tables 5.1** to **5.2,** we have compared the subject device, COR12 ECG, to the predicate, Vyntus ECG cleared under K150810 for equivalence of:

Indications, Patient Population and Environment of Use –
Both devices are the same indications for use which include measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper recording ECG signals.

The patient population and environment of use are identical.

- The patient population from 4 years on and a minimum weight of 20 kg.
- The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital)..

Discussion – The subject and predicate device are identical.

Prescription-Use Only – Both devices are prescription-use only.
Discussion – There is no difference in the type of device as a prescription device; thus, they are substantially equivalent.

Design, Technology and Principle of Operation – The fundamental design, technology, and principle of operation is measuring ECG signals via impedance from a surface electrode is identical.
Discussion – The subject and predicate devices have the identical technological characteristics for measuring ECG signals.

Performance – Non-Clinical Testing Summary -

Biocompatibility – The only component which in in patient contact is the off-the-shelf electrodes. These are 510(k) cleared and we have provided an example of one in the submission.

Bench Testing - The subject and predicate devices are identical as the sponsor is the supplier of the predicate and thus the technical specifications are identical.

- Software life cycle ISO 62304
- IEC 60601-1
- IEC 60601-2-25
- EMC Compatibility IEC 60601-2

Substantial Equivalence Conclusion

The COR12 ECG is substantially equivalent to the predicate in all aspects of substantial equivalence comparison, as it is identical to the predicate, K150810. There are no differences.