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 21, 2016

CorSens Medical Ltd.
% Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St
Binyamina, 30500 IL

Re: K160656
Trade/Device Name: CorSens Device
Regulation Number: 21 CFR 870.2320
Regulation Name: Ballistocardiograph
Regulatory Class: Class II
Product Code: DXR
Dated: September 12, 2016
Received: September 14, 2016

Dear Yoram Levy:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160656

Device Name
CorSens Device

Indications for Use *(Describe)*
CorSens Device records vibrational waveforms produced by the heart contractions and transmitted to the chest wall. CorSens Device may be used as a tool to measure the timing of part of the events in the cardiac cycle for adult population.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

CorSens device

510(k) Number K160656

Applicant's Name: CorSens Medical
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Tel: +972- 3-607-0306

Contact Person: Yoram Levy, Qsite
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Binyamina, Israel 30500
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Yoram@qsitemed.com

Trade Name: ***CorSens Device***

Summary Preparation Date: 04 February, 2015

Classification:

Name: Ballistocardiograph

Product Code: DXR

Regulation No: 21 CFR 870.2320

Class: II

Classification Panel: Cardiology

Device Description:

CorSens Device senses and analyzes the mechanical movement of the heart. This is accomplished by 3 standard ECG electrodes for the ECG signal and with a suitable miniature electronic accelerometer for the mechanical motions.

Intended Use Statement:

CorSens device records vibrational waveforms produced by the heart contractions and transmitted to the chest wall. ***CorSens device*** may be

used as a tool to measure the timing of part of the events in the cardiac cycle for adult population.

Predicate Devices:

The ***CorSens device*** is substantially equivalent to the following market-cleared device:

- **dBG 300 Digital Ballistocardiograph (K081603)** in respect to intended use, clinical indication and technological characteristics.

Reference Devices:

- Visi Mobile Monitoring System (K142827)- in respect the use of 3 ECG leads to capture ECG signals.
- BPCard device diagnostic (K073630)- in respect to the use of a microphone to sense the heart sounds.

Substantial Equivalence to Predicate Devices

CorSens Device has similar intended use and indications for use as its predicate, dBG 300 Digital Ballistocardiograph (K081603).

CorSens Device utilizes the same technology as the cleared dBG 300 Digital Ballistocardiograph (K081603).

CorSens Device has a similar User interface as the cleared dBG 300 Digital Ballistocardiograph (K081603).

Any minor differences in the design do not raise any new questions of safety and effectiveness issues, as verified by performance testing.

Results of tests and validations, performed with the proposed ***CorSens Device*** demonstrates that it is as safe and effective as its primary predicate device, without raising any new safety and/or effectiveness concerns.

Therefore, the CorSens Device is substantially equivalent to its predicate device.

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Performance Standards:

CorSens device complies with:

- ***IEC 60601-1*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- ***IEC 60601-1-2*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

- ***IEC 60601-1-4*** Medical Electrical Equipment-Part 1-4: General requirements for safety- collateral standards: Programmable electrical medical system

- ***ISO 62304*** Medical device software- Software life cycle processes

- ***ISO 14971*** Medical Devices- Application of risk management to medical devices

- ***ISO 15223-1*** Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1.

Performance Bench Tests

The proposed ***CorSens Device*** safety and the efficacy of the system were established by performance lab tests and Software V&V. The proposed ***CorSens Device*** performs according to its specifciation.

The design of ***CorSens Device*** was done in accordance with CorSens Medical quality management system and design controls per 21CFR 820 and ISO 13485. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or identify any new risks.

In addition to the verification and validation testing, a comparison test with the current common clinical practice to measure the timing of the events in the cardiac cycle, an Echocardiogram, was conducted. As ***CorSens Device***

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performance test demonstrates, ***CorSens Device*** can provide accurate timing of part of the event of the cardiac cycle, at least as accurate as the echocardiogram.

Summary of Pre-Clinical and clinical study

CorSens Device is a Ballistocardiograph. The safety and efficacy of the ***CorSens Device*** has been well established in scientific research. Due to the comprehensive clinical studies, scientific research and published literature of Ballistocardiograph devices using the same technology and with its predicate devices, CorSens Medical Ltd. believes that animal and clinical studies are not required to determine the safety and efficacy of the device.

Conclusions

The ***CorSens Device*** was proven to meet the safety and effectiveness endpoints

Substantial equivalence conclusion

The performance tests and the clinical study that were conducted shows that the ***CorSens Device*** is as safe and effective as the listed predicate device without raising any new questions of safety and efficacy