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

October 13, 2017

Mycardio, LLC Dba Sleepimage.
Mr. Robert Schueppert
Manager, Regulatory Affairs
370 Interlocken Blvd.
Suite 650
Broomfield, Colorado 80021

Re: K163696
Trade/Device Name: SleepImage System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: September 11, 2017
Received: September 12, 2017

Dear Mr. Schueppert:

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,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163696

Device Name
SleepImage System

Indications for Use *(Describe)*
The SleepImage System is medical software that establishes sleep quality. The SleepImage system analyzes, displays and summarizes ECG data, typically collected during sleep that is intended for use by or on the order of a Health Care Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management.

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.

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

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MyCardio, LLC
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Tel: 888.975.7464

Date: September 11, 2016

510(K) SUMMARY

SUBMITTER INFORMATION

A. Company Name:	MyCardio LLC dba SleepImage
B. Company Address:	370 Interlocken Blvd. Suite 650 Broomfield, CO 80021, USA
C. Company Phone:	720-708-4209
D. Company Email:	regulatory@sleepimage.com
E. Company Contact:	Robert Schueppert, Manager of Regulatory and Quality

PREPARATION DATE September 11, 2017

DEVICE IDENTIFICATION

A. Device Trade Name:	SleepImage System
B. Device Common Name:	SleepImage
C. Classification Name:	Breathing frequency monitor
D. Regulation Number:	21 CFR 868.2375
E. Product Code:	MNR
F. Device Classification:	Class II
G. Classification Panel:	Unknown

PREDICATE DEVICE

A. Trade Name: CPC Application Software from
M1 Sleep Data Recorder and CPC Application Software (K092003)

Regulation Number: 21 CFR 868.2375
Product Code: MNR

REFERENCE DEVICE

A. Trade Name: Sleep Quality (K070855)
Regulation Number: 21 CFR 868.2375
Product Code: MNR
Rationale: This device has been cleared to analyze ECG data for the purposes of sleep quality measurements and sleep disorder detection without referencing a particular, or a list of particular ECG signal sources or recording devices. The description states the following: "Sleep Quality system takes text format ECG recording into ASCII data format. Most commercially available Holter Monitors devices have this capability. ECG recording data is first collected by a standard Holter device during subject's sleep, is converted into ASCII data format, and is then analyzed by the Sleep Quality system."

INDICATIONS FOR USE

The SleepImage System is medical software that establishes sleep quality. The SleepImage system analyzes, displays and summarizes ECG data, typically collected during sleep that is intended for use by or on the order of a Health Care Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management.

DEVICE DESCRIPTION

The SleepImage System consists of an operator-independent process that automatically analyzes Electrocardiography[1] data using a general purpose computing platform. When provided in addition to the ECG data, the SleepImage System can optionally display accelerometer and oximeter data.

The results of the processed data are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and sleep pathology for the use by or on the order of physicians, trained technicians, or other healthcare professionals.

The data output establishes sleep quality and allows the healthcare professional to evaluate sleep disorders, where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders.

1 Electrocardiography (ECG or EKG) is defined as the process of recording the electrical activity of the heart over a period of time.

The clinician can create unique patient reports for the patient being evaluated, and configure parameters in the software.

The SleepImage System is a standalone, sleep health evaluation application that provides automated analysis of cardiovascular and respiratory waveforms. Like the predicate device, it processes information recorded during sleep. The SleepImage System is considered to be medical software.

The SleepImage System is being updated from the predicate device, the M1 Sleep Data Recorder and CPC Application Software to operate independent of the dedicated M1 Sleep Data Recorder cleared under K092003.

INTENDED USE

The SleepImage System is medical software that establishes sleep quality, intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders based on Electrocardiogram (ECG) recordings, typically collected during sleep.

The results of these analyses are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and sleep pathology. These presentations and reports are intended to inform or drive clinical management.

The SleepImage System is intended for use on a general-purpose computing platform, it does not monitor or diagnose the patient and does not issue any alarms.

COMPARISON TO PREDICATE DEVICES

The SleepImage System is substantially equivalent in the following technological ways to the intended use and application to the identified predicate device;

- Indications for Use
- Basic design
- Materials used
- Where used
- Standards met

TESTING AND PERFORMANCE DATA

Product Safety Testing - not applicable (software).
Electromagnetic Compatibility and Immunity Testing - not applicable (software).
No other specific guidance document on performance is required for this type of device.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility - not applicable (software).
Sterilization - not applicable (software).
Packaging - not applicable (software).
Bench testing –

- The SleepImage System software is identical in specifications and performance to the original cleared CPC Application Software (predicate - K092003). Repeat bench testing conducted on the SleepImage System was not considered necessary.

- A study was conducted to compare electrocardiography (ECG) analysis and results of the SleepImage System based on simultaneous recordings with alternate ECG collection sources (ECG signal extracted from a typical hospital PSG study and ECG sensors for home use) and the predicate M1 Sleep Data Recorder. The result of this comparison is that the output from the ECG signals from the alternate recordings are in every respect statistically equivalent to the output from ECG signals recorded by the predicate M1 Sleep Data Recorder predicate device.

CONCLUSION

It is the the conclusion of MyCardio LLC that the SleepImage System is substantially equivalent to the predicate device [cleared by the 510(k) process] and presents no new concerns about safety and effectiveness.