August 14, 2019

MyCardio, LLC dba SleepImage.
Robert Schueppert
Manager, Regulatory Affairs
3513 Brighton Blvd, Suite 530
Denver, Colorado 80216

Re: K182618
Trade/Device Name: SleepImage System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR
Dated: August 5, 2019
Received: August 6, 2019

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. 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,

James J. Lee
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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
K182618

Device Name
SleepImage System

Indications for Use

The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults.

The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.

The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

Type of Use

☒ 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

I. SUBMITTER INFORMATION

Contact Robert Schueppert
Manager of Regulatory and Quality
regulatory@sleepimage.com

MyCardio, LLC dba SleepImage
3513 Brighton Blvd, Suite 530
Denver, CO 80216

Phone: 720-708-4200

Date of Preparation August 13, 2019

II. DEVICE IDENTIFICATION

Device Trade Name: SleepImage System

Device Common Name: SleepImage

Classification Name: Breathing frequency monitor

Regulation Number: 21 CFR 868.2375

Product Code: MNR

Device Classification: Class II

Classification Panel: Anesthesiology

III. PREDICATE DEVICE

Device Trade Name: SleepImage System (K163696)

IV. DEVICE DESCRIPTION

The SleepImage System is a Class II Software as a Medical Device (SaMD), intended to aid in the evaluation of sleep disorders, where it may inform or drive clinical management.

The SleepImage System automatically analyzes and displays Electrocardiogram (ECG) and Plethysmogram (PLETH) data. When provided in addition to the ECG or PLETH data, the SleepImage System can optionally analyze and 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 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 for children, adolescents and adults. When oximeter data is available, the SleepImage System will generate the SleepImage Apnea Hypopnea Index (sAHI) to aid healthcare professionals in diagnosis and management of sleep disordered breathing.

The SleepImage System reports results of the automated data analysis, including expected values for sleep quality, sleep duration and sleep pathology based on published peer-reviewed publications, and guidelines for sleep duration (National Sleep Foundation) and sleep apnea (American Academy of Sleep Medicine).

The clinician can view raw data for interpretation, adjust study duration, write clinical notes in the report and make recommendations to patients for further testing, recommend a referral to another clinician and/or recommendations for therapy.

The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional. Due to the intra-night variability of sleep, it is recommended that patients track their sleep over time.

The SleepImage System is a sleep health evaluation application that is indicated for use on a general-purpose computing platform. Like the predicate device, it processes data typically recorded during sleep, using a cloud-based web application.

The SleepImage System is being updated from the predicate device; the SleepImage System cleared under K163696.

V. INDICATIONS FOR USE

The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults.

The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.

The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

VI. COMPARISON TO PREDICATE DEVICE

Like the predicate device (K163696), the SleepImage System subject device (K182618) is Software as a Medical Device (SaMD) designed and intended to establish sleep quality and evaluate sleep disorders. The subject and predicate devices are based on the following same technological elements:

- Both are Software as a Medical Device (SaMD).
- Both are cloud-based web applications, using general-purpose computing platforms.
- Both have the same basic software design, control mechanism and operating principle.
- Both use the same technology to couple Heart Rate Variability and Respiration.
- Both are intended to Inform or Drive Clinical Management of sleep disorders.

The following similarities / differences exist between the subject and predicate devices:

Modification #1: Plethysmography (PLETH) is added as valid input signal for Cardiopulmonary Coupling (CPC) analysis. This modification required a change in the software to add PLETH as an alternative to electrocardiogram (ECG) as valid input signal.

CPC processing remains unchanged and is the same for both input signals using peak-to-peak intervals of heart (pulse) rate variability coupled with respiration.

Report output and user instructions are expanded to accommodate this change.

Modification #2: Calculation of a SleepImage Apnea Hypopnea Index (sAHI) is added to aid healthcare professionals in diagnosis of sleep disordered breathing. This modification required a change in the software to automatically calculate the sAHI output, using SpO_2 data input already cleared in the predicate device.

sAHI calculations are performed and presented using American Academy of Sleep Medicine (AASM) guidelines and thresholds to categorize sleep apnea as mild; moderate and severe, both in adults and children. The sAHI output is based on calculating desaturations from SpO_2 data and based on sleep time.

Report output and user instructions are expanded to accommodate this change.

VII. SUBSTANTIAL EQUIVALENCE

Substantial equivalence is established through a phased clinical evaluation process and performance testing, referencing American Academy of Sleep Medicine (AASM) published guidelines and recommendations.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided based on Guidance Documents for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and "*Software as a Medical Device (SaMD): Clinical Evaluation"*.

Clinical Evaluation

In accordance with FDA Guideline for clinical evaluation of Software as a Medical Device (SaMD), reference data from over 2,000 sleep studies obtained from prospective clinical trials in children and adults that were conducted for the same intended use as the subject device were analyzed.

Each sleep recording obtained and utilized for this clinical evaluation contained ECG, PLETH and SpO_2 signals, collected simultaneously. Study results from children (n=1334) are all based on PSG studies and study results from adults (n=761) are reported separately from PSG (n=189) and HSAT (n=572) in the labeling.

Tests for modification #1 were performed to compare agreement of the automated output from CPC analysis using the predicate device to compare PLETH vs ECG as the input signals for the test. The tests were performed based on pre-determined agreement in outcomes. All parameters tested exceeded the thresholds set for the tests. Reference is made to published results from the American Academy of Sleep Medicine (AASM) Inter-scorer Reliability Program: Sleep Stage Scoring, published in the Journal of Clinical Sleep Medicine reporting the average agreement for sleep stage scoring among expert scorers in accredited sleep centers using PSG, which is on average 82.6%.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3525994/

Tests for modification #2 were performed (1) to compare agreement from SleepImage Apnea Hypopnea Index (sAHI) vs. manual human scoring of Apnea Hypopnea Index (AHI) using American Academy of Sleep Medicine (AASM) scoring criteria for mild, moderate and severe sleep apnea in pediatric and adult patients and (2) to evaluate sAHI using guidelines issued by the AASM to compare sensitivity and Positive Likelihood Ratio (LR+) against pre-determined thresholds for use in Out Of Center (OOC) sleep diagnostic devices. Guidelines were published in the Journal of Clinical Sleep Medicine.
https://www.ncbi.nlm.nih.gov/pubmed/22003351

All parameters tested exceeded the thresholds set for the tests.

ECG signal processing and CPC analysis in the subject device is unchanged, the output of CPC analysis from ECG signal therefore remains identical to the predicate device.

Labeling and Instructions for Use have been updated with information on performance results and references to academic guidelines from the American Academy of Pediatrics stating that clinicians should familiarize themselves with the sensitivity and specificity of the test against a full polysomnography test to determine if it is conclusive to be reliable for clinical diagnosis.

Validation and verification was performed to verify that the software modifications did not have any adverse impact on the functionality of the SleepImage System. Software verification and validation included software code reviews as well as labeling and user manual review.

The verification and validation testing demonstrate that both new feature requirements have been satisfied and safety and effectiveness has not been inadvertently affected by modifications to the system.

VIII. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

Product Information	**Subject Device**	**Predicate Device**
Device	Medical Software (SaMD)	Medical Software (SaMD)
510(k) #	K182618	K163696
Trade / Product Name	SleepImage System	SleepImage System
Regulation No.	21 CFR 868.2375	21 CFR 868.2375
Product Code	MNR	MNR
Classification	II	II
Panel	Anesthesiology	Anesthesiology
Manufacturer	MyCardio LLC	MyCardio LLC
Environment of Use	N/A (Software)	N/A (Software)
Indications for Use	The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management	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 Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management.

	for children, adolescents and adults. The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.	
Intended Use	The SleepImage System is Software as a Medical Device (SaMD) 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) or Plethysmogram (PLETH) 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 for children, adolescents and adults. The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional. The SleepImage System is intended for use on a general-purpose computing	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 is not a monitor and does not issue any alarms.

	platform, it is not a monitor and does not issue any alarms.	
Principle of Operation	The SleepImage System is a cloud-based web application Software as a Medical Device (SaMD).	The SleepImage System is a cloud-based web application Software as a Medical Device (SaMD).
Computer Requirements	General-purpose computing platform with internet connection	General-purpose computing platform with internet connection
Software	Cloud-based software application that analyzes and displays ECG, PLETH and oximeter data	Cloud-based software application that analyzes and displays ECG and oximeter data
Data Transfer	Data is transferred between user's general-purpose computing platform and cloud-based server, utilizing secure authentication protocols over the Internet	Data is transferred between user's general-purpose computing platform and cloud-based server, utilizing secure authentication protocols over the Internet
Computer Security	Use of secure authentication protocols	Use of secure authentication protocols
Target Population	Children, Adolescents and Adults	Unspecified

IX. CONCLUSION

Clinical evaluation has confirmed that the output of Cardiopulmonary Coupling (CPC) analysis PLETH signal input of the subject device when compared to the ECG signal input of the predicate device are comparable for clinical decisions.

Clinical evaluation has confirmed that the SleepImage System auto-scoring algorithms calculating the SleepImage Apnea Hypopnea Index (sAHI) generate comparable output to human manual scoring of an Apnea Hypopnea Index (AHI) from Polysomnography (PSG) studies, using American Academy of Sleep Medicine (AASM) scoring guidelines for children and adult patients.

The conclusions of these performance tests support the same intended use of the subject device as the predicate device and do not raise any new concerns about safety and effectiveness. It is concluded that the SleepImage System subject device, using either ECG or PLETH for Cardiopulmonary Coupling is substantially equivalent to the predicate device. It is further concluded that despite differences in how the SleepImage Apnea Hypopnea Index (sAHI) is automatically calculated compared to how the Apnea Hypopnea Index (AHI) is manually scored from PSG studies, that the sAHI has demonstrated agreement levels compared to manually scored AHI from PSG studies to be used to aid clinical diagnosis of sleep apnea in children and adults.