2023

SleepImage System: Labeling Change (Letter to File)

Maanya Venigalla

Northeastern University

The SleepImage System is a Class II medical device designed to evaluate and monitor sleep quality by measuring heart rate variability during sleep using a non-invasive chest sensor and proprietary software algorithms. Recently, the device's labeling was updated to include clearer instructions for sensor placement, improved attachment guidelines, and additional troubleshooting information to enhance usability and accuracy for healthcare providers.

Table of Contents

SleepImage System: Labeling Change (Letter to File)

Device Overview

DEVICE: SleepImage System

MyCardio, LLC dba SleepImage.

510(k) NO: K182618(Traditional)

ATTN: Robert Schueppert

3513 Brighton Blvd, Suite 530

Denver CO 80216

PHONE NO: 720 7084205

SE DECISION MADE: 14-AUG-19

The SleepImage System is a medical device manufactured by MyCardio, LLC, which is designed to evaluate and monitor a patient's sleep quality by measuring and analyzing heart rate variability (HRV) during sleep. The device uses a non-invasive sensor that is worn on the patient's chest to record ECG signals throughout the night, which are then analyzed by proprietary software algorithms to provide information on the patient's sleep quality.

Classification and Regulatory Pathway:

The SleepImage System is classified as a Class II device by the U.S. Food and Drug Administration (FDA) under product code PSY for Sleep Monitoring Devices. The device was cleared for marketing in the United States through the 510(k) premarket notification process. The 510(k) number for the SleepImage System is K182618.

Regulations:

The SleepImage System is subject to regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the applicable regulations in Title 21 of the Code of Federal Regulations (CFR). The device is required to comply with the FDA's current Good Manufacturing Practice (cGMP) regulations, as well as other applicable regulations, including labeling and reporting requirements.

Design and Description:

The SleepImage System consists of a non-invasive sensor that is placed on the patient's chest and a software program that analyzes the recorded ECG signals to provide information on the patient's sleep quality. The device is designed to be used by healthcare professionals in sleep clinics or other clinical settings to help diagnose and monitor sleep disorders. The sensor is worn by the patient during sleep and records ECG signals, which are then transmitted to a computer or

other device for analysis by the SleepImage software. The software uses proprietary algorithms to analyze the ECG signals and provide information on the patient's sleep quality, including information on the duration and quality of sleep, as well as any disruptions or abnormalities in the patient's sleep pattern.

Codes:

The SleepImage System is assigned the following product codes by the FDA:

Product Code: PSY - Sleep Monitoring Devices

Regulation Number: 870.2920 - Sleep Monitoring Device

510K Summary

The 510(k) summary for the SleepImage System indicates that the device is a Class II medical device used for the evaluation and monitoring of a patient's sleep quality. The device uses a non-invasive sensor worn on the patient's chest to record ECG signals throughout the night, which are then analyzed by proprietary software algorithms to provide information on the patient's sleep quality. The summary provides information on the device's intended use, indications for use, performance testing, clinical studies, and labeling requirements. The device was cleared for marketing in the United States through the 510(k) premarket notification process, with the 510(k) number K182618.

Labeling Changes

The updated labeling includes additional information related to the proper placement and use of the sensors that attach to the patient's body. Specifically, the changes include:

Clearer instructions for placement: The updated labeling provides more detailed information on the placement of the sensors, including specific anatomical locations where the sensors should be placed on the patient's body. This information is intended to help healthcare providers ensure that the sensors are positioned correctly, which can improve the accuracy of the device's measurements.

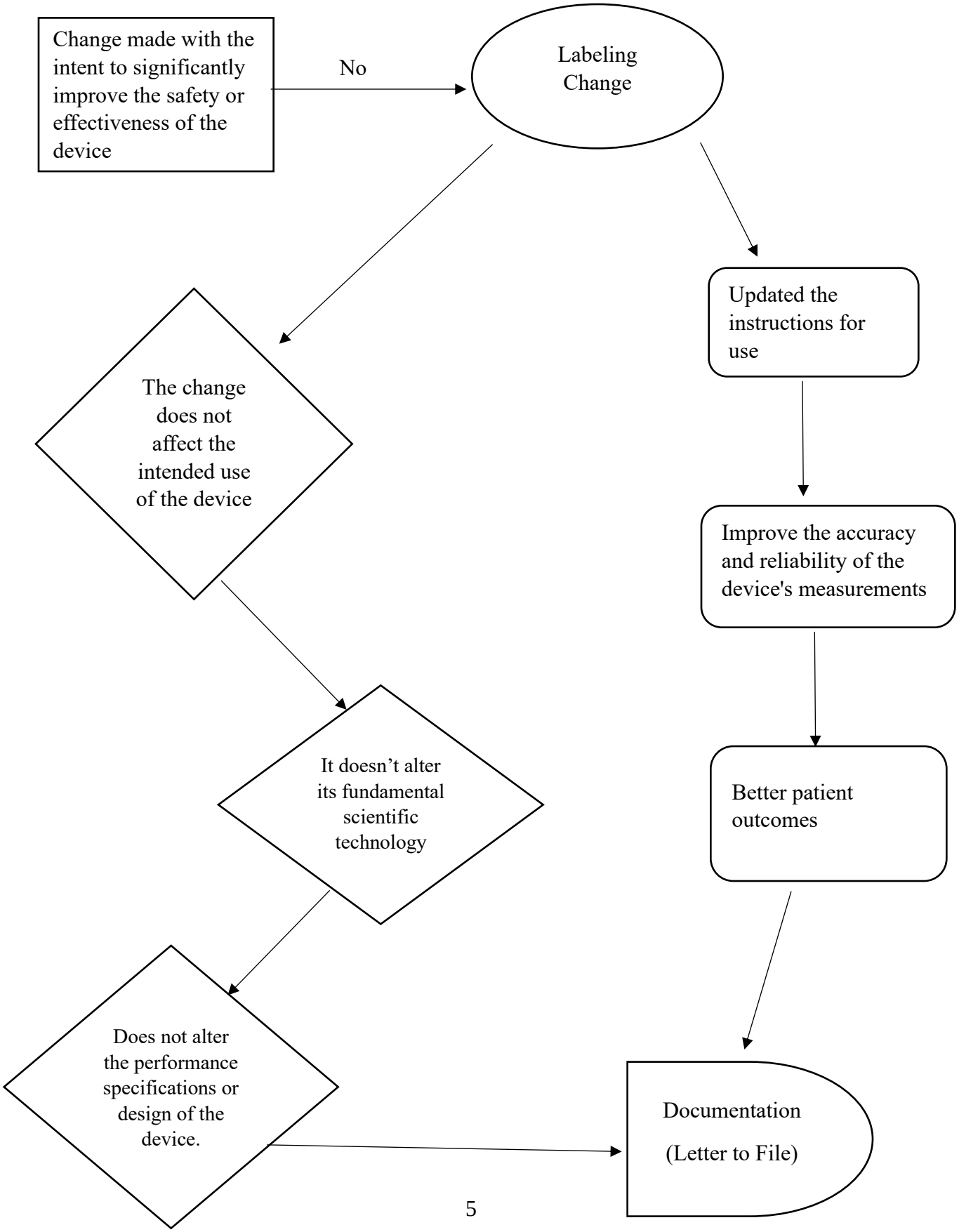
Improved sensor attachment instructions: The labeling now includes more detailed instructions for attaching the sensors to the patient's body. This includes information on how to properly prepare the skin before attaching the sensors, and how to ensure that the sensors are securely attached.

Additional troubleshooting information: The updated labeling includes additional troubleshooting information to help healthcare providers address common issues that may arise during the use of the SleepImage System. This information is intended to help healthcare

providers quickly identify and resolve any issues that may affect the accuracy of the device's measurements.

Overall, these changes are intended to improve the usability and accuracy of the SleepImage System. By providing clearer instructions for sensor placement and attachment, and additional troubleshooting information, we believe that healthcare providers will be better able to use the device effectively, leading to improved patient outcomes.

Labelling Changes: Flow Chart A



Letter to File Document

Business Unit:	MyCardio, LLC dba SleepImage.
Target NPD Release Date:	08/05/2019
Device / Project Name:	SleepImage System
Product Manager:	Robert Schueppert

Catalog #	Description of Device
1	The SleepImage System is a medical device manufactured by MyCardio, LLC, which is designed to evaluate and monitor a patient's sleep quality by measuring and analyzing heart rate variability (HRV) during sleep. The device uses a non-invasive sensor that is worn on the patient's chest to record ECG signals throughout the night, which are then analyzed by proprietary software algorithms to provide information on the patient's sleep quality.

*Additional catalog numbers will be recording in the comment section or attached

This regulatory strategy is an assessment of current product development plans and is subject to change accordingly. Performance claims will be defined in the design inputs/user needs document.

Device Description:

The SleepImage System consists of a non-invasive sensor that is placed on the patient's chest and a software program that analyzes the recorded ECG signals to provide information on the patient's sleep quality. The device is designed to be used by healthcare professionals in sleep clinics or other clinical settings to help diagnose and monitor sleep disorders.

The sensor is worn by the patient during sleep and records ECG signals, which are then transmitted to a computer or other device for analysis by the SleepImage software. The software uses proprietary algorithms to analyze the ECG signals and provide information on the patient's sleep quality, including information on the duration and quality of sleep, as well as any disruptions or abnormalities in the patient's sleep pattern.

Intended Use/Indications for Use:

Prescription Use (Part 21 CFR 801 Subpart D)

Section 1 ☐ **N/A**

US Regulatory Strategy

The SleepImage System is classified as a Class II device by the U.S. Food and Drug Administration (FDA) under product code PSY for Sleep Monitoring Devices. The device was cleared for marketing in the United States through the 510(k) premarket notification process. The 510(k) number for the SleepImage System is K182618.]

- Class of device: II
- Product Code: MNR
- Regulation: 21 CFR 868.2375
- Regulation Name: Breathing frequency monitor
- Submission Type: Exempt, 510k, PMA
- Predicate Device(s) 510(k) #: _____
- Predicate Device(s) Intended Use/Indications for Use: Prescription Use (Part 21 CFR 801 Subpart D)
- PMA*: ____

  ☐ PMA Supplement Type: _____

  ☐ New PMA

*** Attach PMA Change Strategy Meeting Minutes**

UDI Requirements (21 USC 321(h))

Device subject to UDI requirements? If NO, exception must be documented in comments	☒ Yes ☐ No
Device subject to UDI direct marking? If NO, exception must be documented in comments	☒ Yes ☐ No

Section 2

Line Extension Needing Regulatory Assessment ☒ Yes ☐ No

Summary of Changes

We recently made a change to the labeling for the SleepImage System. Specifically, we updated the instructions for use to include additional information on the proper placement and use of the sensors that attach to the patient's body. We believe that this change will improve the accuracy and reliability of the device's measurements, and will ultimately lead to better patient outcomes.

After reviewing the FDA's guidance, we have determined that this labeling change falls under the category of a 'minor change' as defined in the guidance. Specifically, the change does not affect the intended use of the device, nor does it alter its fundamental scientific technology. Furthermore, the change does not alter the performance specifications or design of the device

The assessment of the design change(s) has determined there is,

Flowchart A – Change in labeling?	☒ Yes	☐ No
Flowchart B – Change in technology or performance?	☐ Yes	☒ No
Flowchart C – Is it a materials change?	☐ Yes	☒ No

This assessment is documented using the flowcharts provided in FDA Guidance for Industry and Food and Drug Administration Staff, *Deciding When to Submit a 510(k) for Change to an Existing Device*, dated October 25, 2017. Any required flowcharts **are COMPLETED and ATTACHED** along with additional information as necessary.

Section 3

EU Regulatory Strategy

Refer to Table 1 for the EU Regulatory Strategy.

Rest of World Regulatory Strategy

Create a Standard Technical Document (STED) in current format for international registrations. Targeted markets depend on the final business plan.

Countries Intended for Distribution

Marketing to define priority of countries selected based upon market opportunities. Prioritize using the number "1" as the highest business need and number the rest in descending order.

4	Australia
8	Brazil
3	Canada
7	China
2	Europe
6	Japan
5	Korea
1	U.S.
	Other (be specific):

N/A

Note: Product will be available in counties that do not require registration of medical devices.

Table 1: EU Regulatory Strategy

Technical File / Dossier #:		**Clinical Evaluation**	
Conformity Assessment		**Product Family**	
Class per Rule		**Post Market Clinical Follow-up Required?** ☐ Yes ☒ No	**Certificate Update / Dossier Required?** ☒ Yes ☐ No
Applicable Directives	List all directives applicable to the devices (e.g. Medical Device Directive MDD 93/4/EEC, Pressure Directive 2014/68/EU etc.)		
Required Standards *(include applicable years)*	**EN 1041** Information Supplied by the Manufacturer with Medical Devices **EN ISO 13485** Medical devices – Quality management systems – Requirements for regulatory purposes **EN ISO 14155** Clinical investigation of medical devices for human subjects – Good clinical practice **EN ISO 14971** Medical devices – Application of risk management to medical devices **EN ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements		
Device Specific Standards (Include applicable year and change as necessary)	**EN 62366** Medical devices – Application of usability engineering to medical devices **EN ISO 15883-6** Washer-disinfectors – Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment **EN ISO 17664** Sterilization medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices **EN ISO 17665-1** Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of sterilization process for medical devices		

NOTE: Standard versions are subject to change per the harmonized standards and of other European standards published in the Official Journal of the European Union (OJEU) http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/

References

510(k) Premarket Notification: SleepImage System. K182618. (2019, August 14). Retrieved from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182618.pdf

Center for Devices and Radiological Health. (2019). Retrieved from U.S. Food and Drug Administration: https://wayback.archive-it.org/7993/20201226001029/https://www.fda.gov/medical-devices/510k-clearances/august-2019-510k-clearances

Deciding when to submit a 510(k) for a change to an existing device: Guidance for industry and Food and Drug Administration staff. (2019). Retrieved from U.S. Food and Drug Administration: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

Device Classification: 870.2920 Sleep Monitoring Device. (n.d.). Retrieved from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=1685

How it works. (n.d.). Retrieved from SleepImage: https://www.sleepimage.com/how-it-works

MyCardio, LLC dba SleepImage. (n.d.). SleepImage . (n.d.). Retrieved from https://sleepimage.com/

Schueppert, R. (2023). 7. MyCardio, LLC DBA sleepimage.