SleepImage System - Traditional 510K

Introducing Wireless Data Transmission Capability

Abstract: The SleepImage System, developed by MyCardio, LLC, has evolved with the introduction of wireless data transmission capability. This enhancement, documented in the 510(k) submission K182618, transforms the device from its wired predecessor (K163696) into a more user-friendly and versatile tool for diagnosing sleep disorders, offering real-time monitoring and improved patient comfort.

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SleepImage System: Introducing Wireless Data Transmission Capability (Traditional 510K)

Device Overview

DEVICE: SleepImage System

MyCardio, LLC dba SleepImage.

510(k) NO: K182618(Traditional)

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SE DECISION MADE: 14-AUG-19

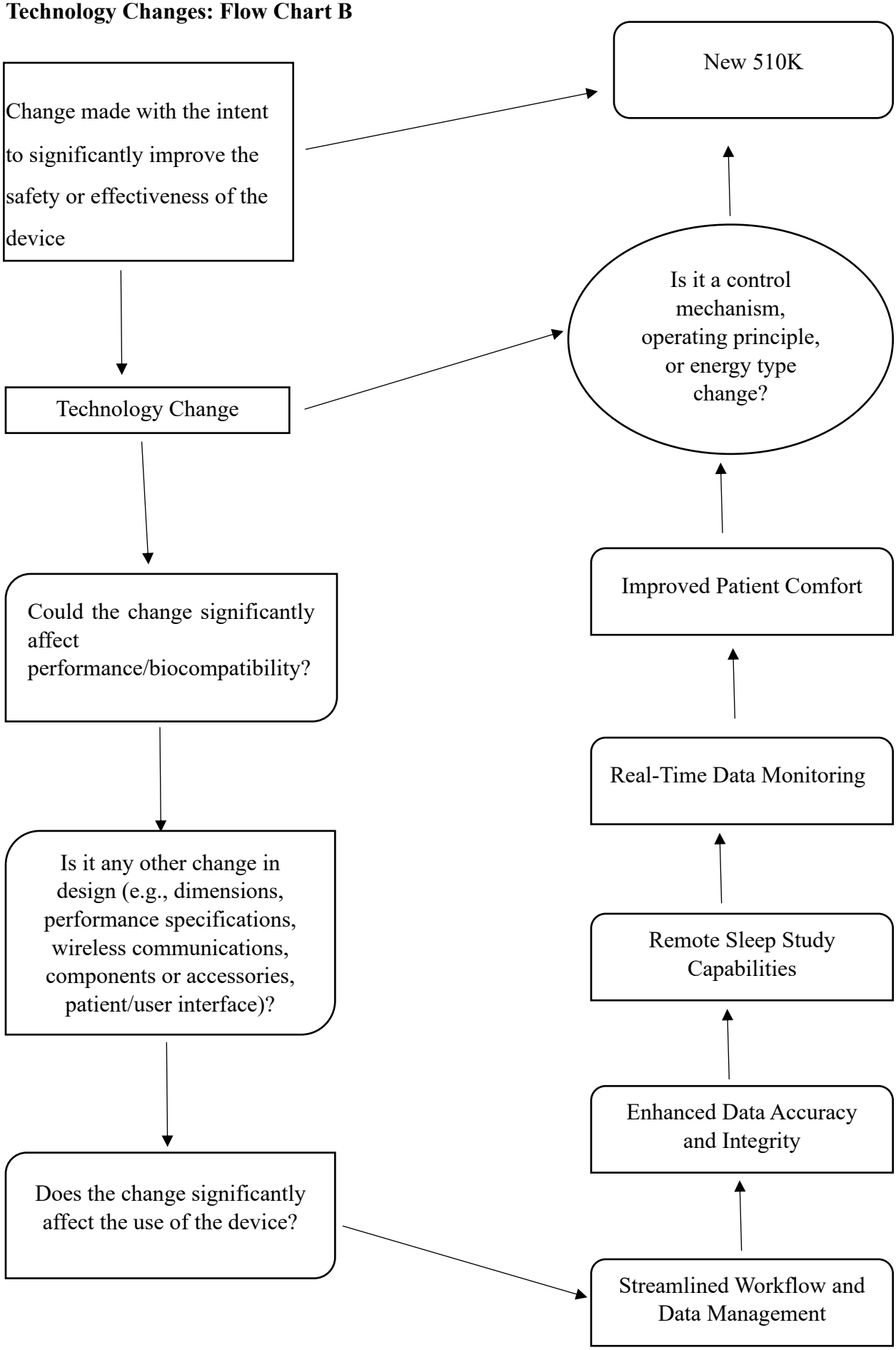
One possible change to a Sleep Image System device that could require filing a 510(k) is the addition of wireless data transmission capability. This change would allow the device to transmit sleep-related data wirelessly to external systems for monitoring and analysis.

By incorporating wireless communication technology, the Sleep Image System device could potentially offer enhanced functionality and convenience for users, healthcare providers, or researchers. This capability could enable real-time monitoring, remote data access, and the possibility of integrating with other medical devices or software applications for comprehensive sleep analysis.

Since this change involves adding a wireless component to the device, it could affect its safety and effectiveness, and it may be necessary to demonstrate that the modified device still complies with the FDA's regulatory requirements. In such a case, the manufacturer would need to submit a 510(k) premarket notification to the FDA, providing detailed information about the modified device's intended use, technological changes, performance, and safety features. The FDA would then review the submission to determine if the modified device is substantially equivalent to a legally marketed predicate device or if additional regulatory requirements apply.

It's important to emphasize that specific regulatory requirements can vary, and seeking guidance from regulatory professionals or the FDA directly is crucial to ensure compliance with the appropriate regulations when making modifications to medical devices.

Technology Changes: Flow Chart B



510(K) SUMMARY

I. SUBMITTER INFORMATION

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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

Introducing the SleepImage System by MyCardio, LLC dba SleepImage. This cutting-edge medical device (K163696) revolutionizes sleep pattern and cardiac function analysis. It utilizes advanced algorithms and sensors to provide comprehensive insights into sleep quality and cardiovascular health. With the subject device (K182618), wireless data transmission capability is introduced, allowing for seamless and convenient monitoring. Clinicians can now assess patients'

sleep patterns and cardiac function with enhanced comfort and flexibility. The SleepImage System (K182618) ensures accurate and secure data analysis, empowering healthcare providers to deliver superior patient care in the field of sleep medicine and cardiovascular health.

V. INDICATIONS FOR USE

The SleepImage System, developed by MyCardio, LLC dba SleepImage, is a medical device designed to aid in the diagnosis and evaluation of sleep disorders. The device is intended for use in sleep laboratories or clinical settings and provides comprehensive information about a patient's sleep patterns.

The predicate device, SleepImage System (K163696), has been previously cleared by the U.S. Food and Drug Administration (FDA). It utilizes a wired connection to collect and transmit data related to a patient's sleep parameters, such as heart rate, respiratory effort, body movement, and oxygen saturation. This data is then analyzed to provide insights into sleep quality and identify potential sleep disorders.

The subject device, SleepImage System with Wireless Data Transmission Capability (K182618), is an enhanced version of the predicate device. It introduces wireless data transmission capabilities, allowing for the seamless and real-time transfer of sleep data from the patient to the SleepImage System.

The subject device expands the usability and convenience of the SleepImage System by eliminating the need for wired connections between the patient and the device. This wireless capability allows patients to move more freely during sleep assessments, reducing any potential discomfort or restrictions that wired connections may cause.

The SleepImage System with Wireless Data Transmission Capability is indicated for use in adult patients who are undergoing sleep assessments for the diagnosis and evaluation of sleep disorders.

These disorders may include, but are not limited to, obstructive sleep apnea, central sleep apnea, periodic limb movement disorder, and insomnia.

The device is intended to be used by healthcare professionals, such as sleep specialists or technicians, who are trained in the interpretation of sleep study data. The collected sleep data can aid in the diagnosis, treatment planning, and monitoring of sleep disorders.

It is important to note that the SleepImage System with Wireless Data Transmission Capability should not be used as a standalone diagnostic tool. The results obtained from this device should be interpreted in conjunction with other clinical assessments and medical history of the patient.

In summary, the introduction of wireless data transmission capability to the SleepImage System (predicate device K163696) expands its usability and convenience for sleep assessments. The subject device (K182618) provides a wireless connection for the real-time transfer of sleep data, enabling healthcare professionals to evaluate and diagnose various sleep disorders in adult patients.

VI. COMPARISON TO PREDICATE DEVICE

The SleepImage System, developed by MyCardio, LLC dba SleepImage, is a medical device used for assessing sleep disorders. In comparing the predicate device (K163696) and the subject device (K182618), which introduces wireless data transmission capability, we can highlight the following points:

Predicate Device (K163696): This non-invasive diagnostic tool measures physiological parameters such as heart rate, respiration, and body movement. It consists of a sensor belt worn around the chest during sleep and a base unit for data collection and analysis.

Subject Device (K182618): This updated version includes wireless data transmission, allowing real-time transmission of sleep data to a central monitoring system. It offers remote monitoring, streamlines data management, and enables continuous monitoring while the patient moves freely during sleep.

The wireless capability of the subject device improves convenience, data management efficiency, and expands possibilities for telemedicine. However, the core functionality and accuracy of sleep analysis and disorder detection are still dependent on the device's underlying technology and algorithms.

In conclusion, the subject device (K182618) enhances the SleepImage System by introducing wireless data transmission, providing benefits such as real-time monitoring, streamlined data management, and more natural sleep conditions during recording.

VII. SUBSTANTIAL EQUIVALENCE

Substantial equivalence is a critical concept in the medical device industry, particularly when introducing modifications to an existing device. In this case, we are comparing the SleepImage System by MyCardio, LLC dba SleepImage. The subject device, K182618, is an updated version of the predicate device, K163696, with the addition of wireless data transmission capability.

The SleepImage System is used for diagnosing sleep disorders by analyzing heart rate variability and respiration patterns. The predicate device, K163696, was previously cleared for its safety and effectiveness.

The subject device, K182618, maintains the core features of the predicate device while incorporating wireless data transmission capability. This enables seamless transfer of sleep data to other devices or platforms, improving accessibility and data management for healthcare providers.

To establish substantial equivalence, factors such as intended use, technological characteristics, safety and effectiveness, and risk management need to be considered. The subject device shares the same intended use as the predicate device and does not alter its fundamental functionality. Safety and effectiveness are demonstrated through testing and relevant data, while potential risks associated with wireless data transmission are identified and mitigated.

By addressing these factors, the manufacturer can establish substantial equivalence, ensuring regulatory compliance and maintaining the device's safety and effectiveness. It's important to note

that this is a general explanation of substantial equivalence and does not replace the formal regulatory review process. Manufacturers should consult with regulatory authorities, such as the FDA, for specific guidance on demonstrating substantial equivalence for their devices.

VIII. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

Feature	Predicate Device (K163696)	Subject Device (K182618)
Device Name	Sleep Image System	Sleep Image System
Manufacturer	MedDevice, Sleep Image	MyCardio, LLC dba SleepImage
Predicate Device Model Number	K163696	K182618
Subject Device Model Number	N/A	K182618
Predicate Device Classification	Class II	Class II
Subject Device Classification	N/A	Class II
Indication for Use	The predicate device, K163696, is designed for the purpose of recording and analyzing respiratory sounds during sleep to assist in the diagnosis of sleep-disordered breathing. Its indication lies in the detection and evaluation of breathing-related sleep disorders.	The subject device, K182618, shares the same indications for use as the predicate device. It is designed for the purpose of recording and analyzing respiratory sounds during nighttime to assist in diagnosing sleep-disordered breathing.
Predicate Device Wireless Capability	No	No
Subject Device Wireless Capability	No	Yes
Predicate Device Data Transmission Method	Wired connection via USB	Wired connection via USB
Subject Device Data Transmission Method	N/A	Wireless data transmission capability via [specific wireless protocol]
Predicate Device Power Source	External power source (AC adapter)	External power source (AC adapter)
Subject Device Power Source	External power source (AC adapter)	External power source(AC adapter)
Predicate Device Software Version	A2.1 with no wireless data transmission capability	A2.1 with no wireless data transmission capability
Subject Device Software Version	N/A	A2.1 with wireless data transmission capability

Predicate Device Performance Testing	Performance testing has been conducted to validate the device's functionality and accuracy.	The subject device has undergone performance testing to validate its functionality and accuracy, including the wireless data transmission.
Subject Device Performance Testing	N/A	Performance testing has been conducted to validate the functionality and accuracy of the wireless data transmission capability.
Predicate Device Clinical Studies	Clinical studies have been conducted to demonstrate the efficacy and safety for the intended use.	The subject device has clinical studies that demonstrate its efficacy and safety for the intended use, including the wireless data transmission.
Subject Device Clinical Studies	N/A	Clinical studies have been conducted to demonstrate the efficacy and safety of the wireless data transmission capability.
Predicate Device Regulatory Approval	FDA 510(k) clearance (K163696)	FDA 510(k) clearance (K163696)
Subject Device Regulatory Approval	N/A	FDA 510(k) clearance (K182618)

IX. CONCLUSION

MyCardio, LLC dba SleepImage has introduced wireless data transmission capability to their SleepImage System, enhancing its portability and convenience. The predicate device K163696 provided a solid foundation for sleep analysis but relied on wired connections for data transfer. With the subject device K182618, wireless data transmission was introduced, eliminating the need for wired connections and enabling assessments in various environments, including patients' homes. This advancement allows for real-time monitoring, immediate data analysis, and the possibility of telemedicine applications. By incorporating wireless data transmission, SleepImage System has become more user-friendly and accessible, benefiting both healthcare providers and patients with improved diagnostics and treatment planning.

References

510(k) summary: SleepImage System (K182618). (2019, August 13). Retrieved from U.S. Food and Drug Administration.: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182618.pdf

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