510(K) SUMMARY

SUBMITTER INFORMATION

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PREPARATION DATE

June 29, 2009

DEVICE IDENTIFICATION

A. Device Trade Name: M1 Sleep Data Recorder and CPC Application Software

B. Device Common Name: M1 Sleep Data Recorder and CPC Application Software

C. Classification Name: TBD

D. Regulation Number: TBD

E. Product Code: TBD

F. Device Class: Class II

G. Classification Panel: TBD

PREDICATE DEVICE

Trade Name: Embletta Gold, 510(k) Number: K073682

DEVICE DESCRIPTION

Cardiopulmonary coupling (CPC) is currently a functional module included as one of many features in Embla's polysomnographic (PSG) presentation software of the predicate device. This can be invoked by the user to provide a CPC analysis from the EKG signals provided by the current multi-channel recorders in Embla's hardware product line. It has been decided to duplicate this presentation software module into its own product line with a separate web based application using a dedicated recorder. Therefore, MyCardio and Embla have developed a single channel (EKG) hardware recording device (M1 Sleep Data Recorder) and associated WEB site (CPC Web Application Software) to present the data and provide graphs and reports for manual diagnosis.

The model M1 Sleep Data Recorder is intended to be used as a sleep quality screening device. The M1 is a small palm size data recorder used with two commercially available EKG patient electrodes. One electrode snaps directly onto the recorder body, while the second electrode snaps onto a short cable in turn connected to a connector on the M1. The M1 is to be attached to the patient at home by the two electrodes and used to record multiple individual sleep periods. Following the home study, the M1 is returned to the clinic and the data is uploaded by the clinician to the CPC Web Application Software.

The CPC Application Software consists of three separate software programs working as a system. (1) CPC Console software – this software is similar to the predicate device presentation software CPC module and receives the data uploaded from the M1 recorder and performs the actual data graphing and reporting. (2) CPC Client software – this software manages the interaction between the user and the M1 device and uploads the analyzed M1 data from the CPC Console to the CPC Web software. (3) CPC Web software – this software creates the user interface screens, manages the data inputted by the user, keeps track of the studies and patient demographics, and provides charts, graphs and reports for manual evaluation of sleep quality screening.

A trained physician would typically review and analyze the charts, graphs and reports created and presented by the CPC Web Application Software. After this screening evaluation, the patient may require further testing and examination for possible treatment.

The battery operated M1 device will be capable of 72 hours (representing approximately 10 overnight studies) of recording to an internal memory.

The general intended environment is the patient home but the device is capable of functioning in any environment where patients can sleep reasonably comfortably.

The users are the general public, trained physicians, trained sleep technicians (RPGST) or people working under the supervision of one of these professionals. The user may or may not possess knowledge of the physiological signals or test criteria.

The M1 Sleep Data Recorder and CPC Web Application Software do not provide any alarms and are not intended as a monitor.

INTENDED USE

Sleep Data Recorder

The M1 sleep data recording device is intended for use by a physician or a trained technician for the collection of physiological (Actigraphy) and Electrocardiogram (ECG) recordings during sleep that will be used for screening different sleep associated disorders.

The intended environment is any dry space used for sleeping.

CPC WEB Application Software

The CPC application software (and associated modules) is intended for use by a physician or a trained technician for the analysis, manipulation and final presentation of physiological (Actigraphy) and Electrocardiogram (ECG) recordings during sleep.

The intended environment is any dry space suitable for the operation of a conventional computer.

The device and software do not monitor or diagnose the patient and do not issue any alarms.

COMPARISON TO PREDICATE DEVICES

The M1 Sleep Data Recorder and CPC Web Application Software is substantially equivalent in the following technological ways to the intended use and application in the identified predicate devices;

- Indications for Use
- Target population
- Basic design and architecture (software)
- Physiological signals recorded
- Where used
- Standards met

The Embletta Gold predicate recording device is a small palm-size portable device that connects to one or more probes or sensors on the patient to record a variety of physiological signals, including EKG. This data is then downloaded into a separate

computer where the Embla PSG application software presents the signals in a format that can be read by a trained technician or physician.

TESTING AND PERFORMANCE DATA

Safety tests have been performed on the M1 Sleep Data Recorder to verify compliance with IEC 60601-1/UL60601-1 and any applicable particular standards in this family of international safety standards to ensure that there are no potential hazards on patients, operators, or the surroundings.

Electromagnetic Compatibility tests according to IEC 60601-1-2 are being performed on the M1 Sleep Data Recorder to ensure that no intolerable electro-magnetic disturbances are introduced.

Immunity tests to IEC 60601-1-2 are being performed on the M1 Sleep Data Recorder to ensure that the device operates satisfactorily in an electromagnetic environment.

The internal testing, verification in various design phases, and validation of performance specifications are currently being completed and the reports will be provided in a supplement to this application.

No other specific guidance document on performance is required for this type of device.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility and Sterilization do not apply. The M1 Sleep Data Recorder is connected to a commercially available EKG electrode, and is not intended to contact the body.

Packaging –

- The M1 Sleep Data Recorder, together with the cables, batteries, screwdriver (to insert the batteries), and a small supply of commercially available EKG electrodes will be packaged in a small pouch.

- The CPC Web Application Software can be purchased by logging on to the SleepImage.com website.

Bench testing – Bench testing with the predicate devices is ongoing at this time. A full report will be provided in a supplement to this application.

CONCLUSION

The EKG signal recorded by the M1 Sleep Data Recorder was compared to EKG signals recorded by qualified sleep technicians using the predicate Embletta Gold recorder. The result of the comparison is that the EKG signal recorded by the M1 Sleep Data Recorder is in every respect clinically equivalent in the context of screening to the EKG signal currently recorded by the predicate device.

The presentation, analysis and reports generated by the CPC Web Application Software for the EKG signal recorded by the M1 Sleep Data Recorder were compared by qualified sleep technicians to the presentation, analysis and reports generated by the CPC module of the PSG application software for EKG signals recorded by the predicate Embletta Gold recorder. The result of the comparison is that the presentation, analysis and reports generated by the CPC Web Application Software are in every respect clinically equivalent to the presentation, analysis and reports generated by the predicate device.

It is therefore the conclusion of MyCardio LLC that the M1 Sleep Data Recorder and CPC Web Application Software are substantially equivalent to devices already on the market [cleared by the 510(k) process] and presents no new concerns about safety and effectiveness.