DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 6, 2015

Infinium Medical
% John O'Brien
Regulatory and Quality Systems Lead
AJW Technology Consultants, Inc
445 Apollo Beach Blvd.
Apollo Beach, Florida 33572

Re: K142244
Trade/Device Name: Cleo Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DXN, DQA, CCK
Dated: January 6, 2015
Received: January 8, 2015

Dear John O'Brien,

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 yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142244

Device Name: CLEO Patient Monitor

The purpose and function of the CLEO patient monitor is to monitor basic physiological parameters including

- NIBP (systolic and diastolic)
- $SpO_2$
- $ETCO_2$

The target population is for adults only.

It can be used in all hospital areas and hospital-type facilities. It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

| | | |
|---|---|---|
| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use<br>(21 CFR 807 Subpart C) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) SUMMARY
# (as required by 807.92)

## I. SUBMITTER

Infinium Medical
12151 62nd Street North #5
Largo, FL 33773

Phone: 727-531-8434
Fax: 727-531-8436

Contact Person: Oz Ozkaya
Date Prepared: August 1, 2014

## REGULATORY CORRESPONDENT

AJW Technology Consultants, Inc
445 Apollo Beach, Blvd
Apollo Beach, FL 33572

Phone: 813-645-2855 x101
Fax: 813-645-2856

Contact Person: John O'Brien
Email: jobrien@ajwtech.com

## II. DEVICE

**Name of Device:** CLEO Patient Monitor
**Common or Usual Name:** Patient Physiological Monitor (without Arrhythmia Detection or Alarm)
**Classification Name:** Monitor, physiological, patient (without Arrhythmia detection or alarms)
**Device Panel:** Cardiovascular
**Regulatory Class:** II
**Product Code:** MWI

**Subsequent Product Codes:**

| Regulation Number | Description | Product Code |
|---|---|---|
| 870.1130 | Noninvasive Blood Pressure Measurement | DXN |
| 870.2700 | Oximeter | DQA |
| 868.1400 | Carbon dioxide gas analyzer | CCK |

## III. PREDICATE DEVICE

The CLEO patent monitor is substantially equivalent in intended use and similar technological characteristics of NIBP, $ETC0_2$, and $Sp0_2$ as the OMNI Express Patient Monitor which is one of the monitors cleared as part of K132229. The internal Infinium CAPNOTRAK $CO_2$ sensor is substantially equivalent in intended use and technological characteristics to the Respironics LoFlo $CO_2$ Sensor which was cleared under K053174.

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission

## IV. DEVICE DESCRIPTION

The CLEO monitor is a comprehensive monitoring system with two or three traces compiling, and processing, analyzing and displaying data from up to three different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The CLEO Patient monitor can be powered by an internal battery pack that provides 3 hours of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

The associated accessories include:

- $Sp0_2$ Finger Sensors
- NIBP Monitor
- Blood Pressure Cuff
- $ETCO_2$ Module

## V. INDICATIONS FOR USE

The purpose and function of the CLEO patient monitor is to monitor basic physiological parameters including

- NIBP (systolic and diastolic)
- $SpO_2$
- $ETCO_2$

The target population is for adults only.

It can be used in all hospital areas and hospital-type facilities. It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

## VI. COMPARISON OF TECHNOLIGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The monitoring of basic physiological parameters is the technological principle for both the subject and predicate devices. It is based on the use of modules and accessories that are either connected internally or externally to the monitors in order to monitor the specific physiological parameter. At a high level, the subject and predicate devices are based on the following same technological characteristics:

- Energy Source
- The monitoring of Non-invasive blood pressure
- The monitoring of pulse oximetry
- The monitoring of End Tidal $CO_2$
- Touch Screen Technology
- Software

Because CLEO Patient Monitor's NIBP subsystem is identical to Suntech Medical's NIBP subsystem cleared under K040799 substantial equivalence was not based on performance testing.

The following technological differences exist between the subject and predicate devices:

- ECG waveform
- Heart Rate Monitoring
- Respiration
- Temperature
- Anesthetic agents
- Physical Dimensions

## VII. PERFORMANCE DATA

The following performance date were provided in support of the substantial equivalence determination

**Biocompatibility Testing**

The product contact materials utilized in the CLEO Patient Monitor have been well characterized chemically and physically and have a long history of safe use in predicate devices and are categorized as Generally Regarded as Safe (GRAS). In addition, all patient contact components have been FDA cleared through the 510(k) Premarket Notification process and have been tested for biocompatibility.

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Infinium device, consisting of the CLEO Monitor, NIBP Monitor and Cuff, $SPO_2$ finger Sensors

and the $ETCO_2$ Module. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

**Software Verification and Validation Testing**
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw could directly result in minor injury to the patient or operator.

**Mechanical Testing**

- $CO_2$ Measurement Accuracy and Drift of Measurement Accuracy
- Gas Sampling Rate Accuracy
- System Response/Rise Time
- Respiratory Rate Accuracy
- Gas Mixture Accuracy
- Interfering Agents
- $SPO_2$ Performance Test
- NIBP Performance Test

**Summary of Non-Clinical Data:**

The Cleo Patient Monitor underwent testing according to several different performance standards. Below is a chart of the different testing that was completed.

| Devices | Performance Test | Standard of Compliance |
|---|---|---|
| CLEO Monitor | NIBP | ANSI/AAMI SP10:1992 and 2002, ANSI/AAMI/IEC 80601-2-30:2009 |
| | $SP0_2$ | EN ISO 9919:2009 |
| | Electrical Safety | IEC 60601-1:2005/ EN 60601-1:2006 |
| | EMC | IEC 60601-1-2:2007 |
| | $ETC0_2$ | 80601-2-55:2011 |

## VIII. CONCLUSIONS

The testing completed demonstrates that the CLEO Patient Monitor exhibits comparable mechanical and functional characteristics to the predicate device in addition to being biocompatible acceptable. Based on those characteristics, the CLEO Patient Monitor is substantially equivalent to the predicate device in safety and effectiveness in addition to being intended for the same uses.