K110603

DEC 16 2011

6 510(k) Summary

A. Device Name

The trade name is "Mobil-O-Graph 24h PWA" with
Hypertension Management Software Client Server (HMS-CS 4.3)

Common/Classification Name: Non-invasive blood pressure measurement system as classified per 21 CFR § 870.1130 (DXN)

B. Submitter

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C. Legally Marketed Predicate Devices

Predicate 1

The Mobil-O-Graph 24h PWA is substantially equivalent to the Mobil-O-Graph New Generation (Mobil-O-Graph NG, K072446).

Predicate 2

The Mobil-O-Graph 24h PWA`s Pulse Wave Analysis (PWA) feature as realized through the combination of Mobil-O-Graph 24h PWA and Hypertension Management Software Client Server (HMS-CS) is substantially equivalent to:
SphygmoCor CvMS (K070795)

D. Device Description

The Mobil-O-Graph 24h PWA is a modified version of the Mobil-O-Graph New Generation (K072446). Hardware, general design and housing are very similar, being different in minor items such as artwork /labeling, etc. Full blood pressure measurement technology, hardware including electrical components, sensors, safety circuits and the cuff are identical to the cleared device. The internal device software (=firmware) algorithms for blood pressure measurement are identical. Minor additions have been made to allow for execution of PWA-measurements. Internal memory has been extended to collect the additional data generated during PWA measurement.

Like the predicate Mobil-O-Graph New Generation (K072446), the new device Mobil-O-Graph 24h PWA is used together with the Hypertension Management Software Client-Server (HMS-CS). Full functionality and technology for read-out, storage, evaluation and display of data related to ambulatory blood pressure monitoring (ABPM) is therefore substantially equivalent.

Like the predicate device SphygmoCor CvMS (K070795), consisting of data acquisition hardware and associated computer software, the Mobil-O-Graph 24h PWA together with its analysis software Hypertension Management Software Client-Server (HMS-CS) is a computerized tool for the assessment of a range of central arterial indices. The Mobil-O-Graph 24h PWA system featuring PWA measures peripheral (brachial) blood pressure and records the peripheral pulse wave. The software HMS-CS utilizes a general transfer function (GTF) to derive an ascending aortic pulse wave from the readings. Measurements and the pulse wave are used to calculate a range of central arterial indices.

The Mobil-O-Graph 24h PWA is used with a standard brachial blood pressure cuff measurement, like the predicate Mobil-O-Graph New Generation. The Mobil-O-Graph 24h PWA is intended for use on those patients where information related to ascending aortic blood pressure is desired. In addition, the Mobil-O-Graph 24h PWA incorporates an option to enable users to carry out and store Pulse Wave Analysis (PWA) over 24 hours, in parallel to regular 24h ambulatory blood pressure measurement.

The Mobil-O-Graph 24h PWA is made up of two primary system components: 1) a modified regular ABPM Mobil-O-Graph New Generation (K072446); 2) proprietary software HMS-CS, current version V4.3.

Full data acquisition and storage of measurements for both ABPM and PWA is realized by the Mobil-O-Graph 24h PWA device itself, without any use of the HMS-CS software. Analysis of raw data and calculation of PWA-related parameters is realized through the HMS-CS software. To calculate and display the PWA results, the Mobil-O-Graph 24h PWA must be coupled via Bluetooth to a physician's computer that is currently running HMS-CS Software.

For PWA measurements, there are two modes, 1 and 2. Mode 1 is called "practice monitoring", where the patient is at the physician's office and has both blood pressure and PWA measurements started manually. Data transfer is directly after completion of the measurement, via Bluetooth wireless technology. PWA parameters are calculated right away, so the physician can evaluate the result while seeing the patient.
Mode 2 is called "24h PWA", where the patient leaves the office and the device takes both measurements in automated mode, over a period of 24 hours. Upon return of the patient (and the device) to the physician, data is transferred completely to the physician's PC for later evaluation.

The Mobil-O-Graph 24h PWA system is available with three different cuff sizes (M, L, XL) based on patient's arm size.

All measurements may be stored and viewed on a computer which is connected to the Mobil-O-Graph 24h PWA via a standard Bluetooth connection. Patient data can be printed using a regular installed office printer, preferably with color capability.

The device does not generate any real-time alarms. It does not provide diagnosis. Clinical judgment and experience are required to evaluate and interpret the information provided.

E. Indications for Use

The Mobil-O-Graph 24h PWA system featuring PWA is an automated microprocessor controlled ambulatory blood pressure monitor (ABPM) which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual adult patient (in the patient's environment) for a session which may last 24 hours.

The Mobil-O-Graph 24h PWA in combination with Hypertension Management Software Client Server (HMS-CS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. Use of the Augmentation Index AIx only is restricted to patients of age 40 and above.

It is used with a standard cuff blood pressure measurement.

It is used in those patients where information related to the ascending aortic blood pressure is desired but in the opinion of the physician, the risk of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

F. Substantial Equivalence Summary

1. The Mobil-O-Graph 24h PWA is substantially equivalent in technological characteristics and intended use to the Mobil-O-Graph New Generation (K072446).

2. The Mobil-O-Graph 24h PWA's PWA feature being realized through use of the HMS-CS software is substantially equivalent to the software-part of:
   SphygmoCor CvMS (K070795)

G. Technological Characteristics Comparison

The Mobil-O-Graph 24h PWA and the Mobil-O-Graph New Generation (K072446) are substantially identical in design and technology. With the exception of the Mobil-O-Graph 24h PWA's PWA functionality, the intended uses of these two devices are the same. Like the Mobil-O-Graph New Generation, the primary input signal to the Mobil-O-Graph 24h PWA comes from the non-invasive blood pressure measurement via the brachial cuff. The internal firmware of the Mobil-O-Graph 24h PWA is a modified version of that included in the Mobil-O-Graph New Generation.
The Mobil-O-Graph 24h PWA`s firmware module incorporates minor changes for setting an associated measurement protocol to permit PWA measurement. A detailed comparison of the technological similarities between these two devices can be found in section 12 (SE comparison section).

I.E.M. GmbH has identified one predicate device for the Mobil-O-Graph 24h PWA`s PWA feature.
The PC-software HMS-CS that is used together with the Mobil-O-Graph 24h PWA, includes algorithms (called ARCSolver) for Pulse Wave Analysis (PWA) which provide equivalent performance to that of the SphygmoCor CvMS, for the corresponding parameters.
Technological basis for the raw data acquired and a comparison of the measurement principles are found in the document 12_SE-Comparison, section 12.3d Substantial Equivalence raw data for PWA calculation.

H. Performance Testing
The hardware of the new device Mobil-O-Graph 24h PWA is almost identical to the hardware of the approved Mobil-O-Graph New Generation. Hence, both devices meet the relevant portions of the following standards:

- SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(Manual, electronic or automated sphygmomanometers
- IEC 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
- ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

Evidence is provided in the original 510(k) section 18 "Performance Testing".

In Addition, the Mobil-O-Graph 24h PWA and HMS-CS software have undergone internal hardware and software verification and validation testing including, but not limited to, utilization of a software lifecycle process as required by IEC 62304, to ensure that it complies with its performance requirements.

In addition, a clinical study comparing the Mobil-O-Graph 24h PWA with HMS-CS and the SphygmoCor CvMS has been conducted and it has demonstrated that the devices performed substantially equivalently with regard to their ability to provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. Evidence is provided in this present document, section F "Substantial Equivalence Summary" and the original 510(k), section 18

I. Conclusions

I.E.M. GmbH has demonstrated Mobil-O-Graph 24h PWA is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2011

I.E.M. GmbH
c/o Mr. Peter Knipp
Regulatory Affairs
Cockerillstr. 69
Stolberg 52222
GERMANY

Re: K110603
Device Name: Mobil-O-Graph 24h PWA and Hypertension Management Software Client Server (HMS-CS), Version 4.3
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: October 18, 2011
Received: October 20, 2011

Dear Mr. Knipp:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

K110603

5 Indications for Use Statement

510(k) Number:

Device Name: Mobil-O-Graph 24h PWA used with Hypertension Management-Software Client-Server (HMS-CS).

The Mobil-O-Graph 24h PWA system featuring PWA is an automated microprocessor controlled ambulatory blood pressure monitor (ABPM) which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual adult patient (in the patient's environment) for a session which may last 24 hours.

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Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 12/16/2011

Division of Cardiovascular Devices

510(k) Number K110603