DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 19, 2016

I.E.M. GmbH
Hella Witt
Regulatory Affairs
Cockerillstr.69
Stolberg, 52222 DE
Germany

Re: K153557
Trade/Device Name: ABPM 7100, Hypertension Management Software version 5.0
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 15, 2016
Received: June 20, 2016

Dear Hella Witt:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153557

Device Name
ABPM 7100
used with the application software Hypertension Management Software (HMS)

Indications for Use *(Describe)*

The ABPM 7100 is an automated, microprocessor controlled ambulatory blood pressure monitor (ABPM) which records, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual patient (in the patient's environment) for a session which may last 24 hours. Ambulatory monitoring is not supported for the 14-20 cm cuff size.

It is used with a standard upper-arm cuff for blood pressure measurement.

The ABPM 7100 in combination with the Hypertension Management Software (HMS) provides a derived ascending aortic blood pressure wave form and a range of central arterial indices. It is used in those adult 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Section 05: 510(k) Summary

Submission Sponsor and Correspondent

I.E.M. GmbH
(Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH)
Cockerillstraße 69
52222 Stolberg
Germany

Phone: +49 2402 9500 75
Fax: +49 2402 9500 11
Contact: Hella Witt

FDA Establishment Registration # 9617476

Date prepared: December 2015

Device identification

Trade Name	**ABPM 7100** with Hypertension Management Software
Common name:	Noninvasive blood pressure measurement system
Classification Regulation:	CFR 870.1130
Product Code:	DXN
Device Class:	Class II
Classification Panel:	Cardiovascular

Legally Marketed Predicate Device

K140928, ABPM 7100 PWA with Hypertension Management Software Client Server 4.7

Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Device Description

The ABPM 7100 applies the oscillometric principle for blood pressure measurements.
The ABPM 7100 consists of the following hardware:

- the ABPM 7100 recorder
- the brachial blood pressure cuff

The ABPM 7100 is available with five different cuff sizes to adapt to the patient's arm size.

Initially, the device is prepared for a new patient and measurements are started. Measurement data is recorded and stored in the device's memory. The data can then be transmitted to a computer in the physician's office via Bluetooth or cable for storage, presentation and analysis.
Central Blood Pressure (CBP) calculation is realized through Pulse Wave Analysis, conducted by the Hypertension Management Software with CBP Upgrade.

Indications for Use:

- The ABPM 7100 is an automated, microprocessor controlled ambulatory blood pressure monitor (ABPM) which records, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual patient (in the patient's environment) for a session which may last 24 hours. Ambulatory monitoring is not supported for the 14-20 cm cuff size.
- It is used with a standard upper-arm cuff for blood pressure measurement.
- The ABPM 7100 in combination with the Hypertension Management Software (HMS) provides a derived ascending aortic blood pressure wave form and a range of central arterial indices. It is used in those adult 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.

Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Device Comparison Summary

Trade name	**ABPM 7100**	**ABPM 7100**
Manufacturer	I.E.M GmbH	I.E.M GmbH
510(k) Number	K140928	K153557
Product Code	DXN	DXN
Regulation Number	870.1130	870.1130
Class	II	II
Regulation Name	Non-Invasive blood pressure measurement system	Non-Invasive blood pressure measurement system
Sterile	non-sterile	non-sterile
Single-Use	NO	NO
Power	2 alkaline 1.5 V batteries (AA) or rechargeable 1.2 V (AA)	2 alkaline 1.5 V batteries (AA) or rechargeable 1.2 V (AA)
Measurement principle	Oscillometric	Oscillometric
Complies with ISO 81060-2	YES	YES
Cuff	4 cuff sizes	5 cuff sizes
Latex free	YES	YES
Complies with ISO 10993-1	YES	YES
Electrical safety testing passed	YES	YES

Table A : Device technical comparison

Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Table B: Comparison IEM Analysis Software

Trade name analysis software	**Hypertension Management Software Client Server (HMS CS)**	**Hypertension Management Software (HMS)**
Software version	HMS CS 4.7-US	HMS 5.0
Manufacturer	I.E.M GmbH	I.E.M GmbH
510(k) Number	K140928	K153557
Product Code	DXN	DXN
Regulation Number	870.1130	870.1130
Class	II	II
Regulation Name	Non-Invasive blood pressure measurement system	Non-Invasive blood pressure measurement system
Patient management	List, select from list, modify, delete, import, export	List, select from list, modify, delete, import, export
Overview of measurement data	Overview of all measurements with date/time and type	Overview of all measurements with date/time and type
Print report with patient data, graph and comments	YES	YES
Pulse Wave Analysis	Generally accessible with HMS CS 4.7	Accessible with HMS 5.0 and CBP Upgrade license
Compatibility with other devices	Common database for the data collected by compatibly I.E:M. devices	Compatibility with ABPM 7100

Table B: Technical comparison analysis software

Substantial Equivalence Discussion

Full blood pressure measurement technology, hardware including electrical components, sensors and safety circuits are the same as of the cleared device. The embedded device software (=firmware) algorithms for blood pressure measurement are the same.

Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Functionality and technology for read-out, storage, evaluation and display of data related to ambulatory blood pressure monitoring (ABPM) and Pulse Wave Analysis is substantially equivalent. Modifications for the customization of the software followed written internal procedures that implement the processes described in FDA Guidance "General Principles of Software Validation", and Risk Management conducted in accordance with ISO 14971. All required software testing was completed as part of the software verification and validation, and all tests passed.

Following device modifications, the ABPM 7100 in combination with the Hypertension Management Software (HMS) meets all the requirements for overall design. Testing confirms that the design output meets the design inputs. The ABPM 7100 with HMS passed all testing, which supports the claims of substantial equivalence and safe operation.

The ABPM 7100 passed all testing in accordance with applicable voluntary standards for Electrical safety, electromagnetic compatibility and biocompatibility.

Performance testing according to recognized standards confirms compliance with the particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment.
Accuracy testing of blood pressure measurements was conducted in sitting position with adults and children (age group 3-12 years), and covered the new cuff size (14-20 cm). Ergometer validation conducted for ambulatory monitoring did not include the new cuff size (14-20 cm)
The clinical validation demonstrates adequate NIBP accuracy in accordance with ISO 81060-2, and shows that product specifications are met in compliance to the intended use. Accuracy tests were conducted according to
ISO 81060-2: 2013

- Section 5.2.4.2 (same arm sequential measurements), and
- Section 5.2.6 (additional requirements for use in ambulatory monitoring), applying the opposite arm simultaneous method for the ergometer validation.

Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Test results - Same arm sequential measurements (ISO 81060-2):

Mean error of determination (Criterion 1)			
	Mean error and (sd)	**Acceptance for mean error and sd**	**Judgment**
SBP	1.9 mmHg (6.6 mHg)	± 5.0 mmHg (8.0 mmHg)	Pass
DBP	-2.0 mmHg (5.5 mmHg)	± 5.0 mmHg (8.0 mmHg)	Pass
Standard deviation of averaged paired determination per subject (Criterion 2)			
	Standard deviation	**Maximum permissible standard deviation**	**Judgment**
SBP	5.44 mmHg	6.68 mmHg	Pass
DBP	4.48 mmHg	6.65 mmHg	Pass

Test results – Ambulatory monitoring (ergometer validation)

Mean error of determination (Criterion 1)			
	Mean error and (sd)	**Acceptance for mean error and sd**	**Judgment**
SBP	-0.2 mmHg (7.2mmHg)	± 5.0 mmHg (8.0 mmHg)	Pass
DBP	-1.2 mmHg (6.3 mmHg)	± 5.0 mmHg (8.0 mmHg)	Pass
Standard deviation of averaged paired determination per subject (Criterion 2)			
	Standard deviation	**Maximum permissible standard deviation**	**Judgment**
SBP	4.00 mmHg	6.95 mmHg	Pass
DBP	4.04 mmHg	6.84 mmHg	Pass

Traditional 510(k)	**ABPM 7100** **Section 05: 510(k) Summary**	

Conclusion

From Risk Assessment and device testing I.E.M. concludes that the modified device performs as well and is as save as the predicate device. Performance testing confirms that product specifications are met in accordance with the technological characteristics and the intended use.

The modified ABPM 7100 meets all the stated requirements for overall design, performance, biocompatibility, electrical safety and electromagnetic compatibility. The device passed all testing in accordance with the applicable voluntary international standards.

The ABPM 7100 with Hypertension Management Software are substantially equivalent to the predicate device ABPM 7100 with HMS CS.