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

June 14, 2017

PAR Medizintechnik GmbH & Co. KG
Thomas Fischer
Sachsendamm 6
10829 Berlin
Germany

Re: K170966
Trade/Device Name: TONOPORT VI
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 12, 2017
Received: May 15, 2017

Dear Thomas Fischer:

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,

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

Enclosure

4 Statement of Indications for Use

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)*
K170966

Device Name
TONOPORT VI

Indications for Use *(Describe)*

The TONOPORT VI is a small-size, lightweight, portable, non-invasive blood pressure (NIBP) monitor for ambulatory measurement of the blood pressure by the oscillometric method. The cuff is borne on the upper arm and an electrical pump in the device generates the pressure in the cuff. The TONOPRT VI is powered by two AA size batteries (alkaline or rechargeable NiMH batteries). The device records up to 400 blood pressure measurements at predefined intervals. In order to assess the measurements, the stored data can be transmitted via a RS-232, USB 1.1 or USB 2.0 interface to a PC for further evaluation or archiving purposes by analysis software.

TONOPORT VI is intended to be used for measuring the systolic, diastolic, mean arterial blood pressure and the heart rate of human beings.
The intended patient populations are adults and children (but not neonates) with a circumference of the upper arm in the range of 17 to 42 cm.

TONOPORT VI is a prescription device in health care medicine and is intended for use following consultation and instruction by a physician (family doctor, specialist or hospital). It can be used, if the physical condition of the patient allows an automatic, non-invasive blood pressure measurement. Preparation and application of the TONOPORT VI is done by medically trained staff. The patient does not operate with the TONOPORT VI by himself. TONOPORT VI is not intended to be used in intensive care medicine or for alarming of life-threatening conditions.

A measurement with TONOPORT VI can be combined with other measurements and medical examinations at the patient that a diagnosis about the patient's health condition depends not alone from the measurement of the TONOPORT VI.

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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PAR Medizintechnik GmbH & Co. KG	*Special 510(k) TONOPORT VI*

5 510(k) Summary

Table 2: Submitter information

Submitter:	PAR Medizintechnik GmbH & Co. KG Sachsendamm 6 10829 Berlin Germany
Contact person:	Mr. Thomas Fischer Research and development department PAR Medizintechnik GmbH & Co. KG E-mail: info@par-berlin.com Phone: +49 30 235070 10 Fax: +49 30 2138542
Date:	March 29th, 2017

Table 3: Device information

Device:	Trade name:	TONOPORT VI
	Common name:	Non-Invasive Blood-Pressure Monitor
	Classification name:	Non-invasive blood pressure measurement system (21 CFR 870.1130, Product Code DXN, Class II)
Legally marked device:	Device name:	TONOPORT V
	510(k) number:	K012647

5.1 Device Description

Table 4: Device description

Device functions:	The TONOPORT VI measures the blood pressure non-invasively and provides the systolic, diastolic, mean arterial blood pressure and the heart rate of human beings. The cuff is borne on the upper arm of the patient and an electrical pump in the device generates the pressure in the cuff. The TONOPRT VI is powered by two AA size batteries (alkaline or rechargeable NiMH batteries). The device records up to 400 blood pressure measurements at predefined intervals. In order to assess the measurements, the stored data can be transmitted via a RS-232, USB 1.1 or USB 2.0 interface to a PC for further evaluation or archiving purposes by analysis software. It is intended to get used by physicians (primary care physician, specialists and hospitals).

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Basic scientific concept:	The blood pressure is measured by the oscillometric method. The criteria for this method are the pressure pulsations superimposed with every systole on the air pressure in the cuff. In order to measure the blood pressure, a blood pressure cuff wrapped around the upper arm needs to be inflated and subsequently deflated.
Device design:	The TONOPORT VI is a small-sized, light weighted and portable NIBP monitor with an easy to read display.
Used materials:	Polycarbonate (PC) and acrylonitrile butadiene styrene (ABS) for the case and plastic foil for the labels of the device. Tested biocompatible materials (Nylon and PVC) are used for the cuffs.
Physical properties:	Size: width: 73.0 mm / height: 27.0 mm / depth: 108.0 mm Weight: under 190 g, incl. batteries Connectors: cuff, USB and RS-232 connector

5.2 Indications for Use

The TONOPORT VI is a small-size, lightweight, portable, non-invasive blood pressure (NIBP) monitor for ambulatory measurement of the blood pressure by the oscillometric method. The cuff is borne on the upper arm and an electrical pump in the device generates the pressure in the cuff. The TONOPRT VI is powered by two AA size batteries (alkaline or rechargeable NiMH batteries). The device records up to 400 blood pressure measurements at predefined intervals. In order to assess the measurements, the stored data can be transmitted via a RS-232, USB 1.1 or USB 2.0 interface to a PC for further evaluation or archiving purposes by analysis software.

TONOPORT VI is intended to be used for measuring the systolic, diastolic, mean arterial blood pressure and the heart rate of human beings.

The intended patient populations are adults and children (but not neonates) with a circumference of the upper arm in the range of 17 to 42 cm.

TONOPORT VI is a prescription device in health care medicine and is intended for use following consultation and instruction by a physician (family doctor, specialist or hospital). It can be used, if the physical condition of the patient allows an automatic, non-invasive blood pressure measurement. Preparation and application of the TONOPORT VI is done by medically trained staff. The patient does not operate with the TONOPORT VI

by himself. TONOPORT VI is not intended to be used in intensive care medicine or for alarming of life-threatening conditions.

A measurement with TONOPORT VI can be combined with other measurements and medical examinations at the patient that a diagnosis about the patient's health condition depends not alone from the measurement of the TONOPORT VI.

5.3 Comparison of the TONOPORT VI and the predicate device

The TONOPORT VI is substantially equivalent and employs the same functional technology as the predicate device TONOPORT V.

Table 5: Device comparison

Characteristic	**Subject device** TONOPORT VI	**Primary predicate device** TONOPORT V (510(k) -No.: K012647)	**Explanation of the differences**
Product code	DXN	DXN	Identical
Classification number	21 CFR 870.1130	21 CFR 870.1130	Identical
Common name	Non-Invasive Blood-Pressure Monitor	Non-Invasive Blood-Pressure Monitor	Identical
Class	Class II	Class II	Identical
Intended use	The TONOPORT VI measures and stores the blood pressure data (systolic pressure, diastolic pressure and heart rate) at human beings. The blood pressure can be measured several times at the physician or up to 400 times during a long-term monitoring with one set of fully charged batteries. Medically trained staff has to apply the device and the physician has to analyze the results. The patient does not operate with the TONOPORT VI by himself. The stored data can be transmitted to a PC based application via serial interface for analysis and evaluation.	The TONOPORT V measures and stores the blood pressure data (systolic pressure, diastolic pressure and heart rate) at human beings. The blood pressure can be measured several times at the physician or up to 200 times during a long-term monitoring with one set of fully charged batteries. Medically trained staff has to apply the device and the physician has to analyze the results. The patient does not operate with the device by himself. The stored data can be printed directly on a printer and/or transmitted to a PC-based application via serial interface for analysis and evaluation.	Equivalent The storage capacity is increased and the transmission interfaces are state of the art for the clearance times. These changes are documented and do **not** influence the indications for use.

Characteristic	Subject device TONOPORT VI	Primary predicate device TONOPORT V (510(k) -No.: K012647)	Explanation of the differences
Indications for use	Target population: Adults and children, but **not** neonates Anatomical site: Upper arm (see section 0) Where used: In hospital and at home (following consultation and instruction by a physician)	Target population: Adults and children, but **not** neonates Anatomical site: Upper arm Where used: In hospital and at home (following consultation and instruction by a physician)	Identical
Design	 New and good looking ergonomic design of the case and the user interface	 Functional design of the case and the user interface	Equivalent The changes of the case ergonomics and the user interface that enhance the operator's and patient's convenience are documented and are **not** relevant for the indications for use.

Characteristic	Subject device TONOPORT VI	Primary predicate device TONOPORT V (510(k) -No.: K012647)	Explanation of the differences
Display	 27.0 mm x 58.0 mm (width to height)	 30.0 mm x 10.5 mm (width to height)	Equivalent The change of the ergonomics of the user interface into a clear and easy to read display that increases the safety of the device and enhance the convenience are documented.
Dimensions and weight	Smaller with lower weight compared to TONOPORT V	Small size and low weight	Equivalent The changes in dimensional specifications are documented, do not affect the indications for use and enhance the operator's and patient's convenience.
Width	73.0 mm	80.0 mm	
Height	27.0 mm	27.0 mm	
Depth	108.0 mm	100.0 mm	
Weight	Approximately 190 g with batteries	Approximately 199 g with batteries	
Communication	Measurement settings of the device and the read out of the stored data can be done via serial interface	Measurement settings of the device and the read out of the stored data can be done via serial interface	Identical
Event marking	By pressing the START STOP Button	By pressing the START STOP Button	Identical
Energy source	Powered by two AA size batteries (alkaline or NiMH batteries).	Powered by two AA size batteries (alkaline or NiMH batteries).	Identical

Characteristic	Subject device TONOPORT VI	Primary predicate device TONOPORT V (510(k) -No.: K012647)	Explanation of the differences
Storage capacity	Up to 400 measurements	Up to 200 measurements	Equivalent The evaluation of user needs showed that more storage capacity is need. The change is documented and do not influence the indications for use.
Measuring method	Oscillometric measuring method during deflation of the cuff	Oscillometric measuring method during deflation of the cuff	Identical
Measuring range	systolic pressure 60 to 260 mmHg diastolic pressure 40 to 220 mmHg pulse rate (HR) 35 to 240 min^{-1}	systolic pressure 60 to 260 mmHg diastolic pressure 40 to 220 mmHg pulse rate (HR) 35 to 240 min^{-1}	Identical
Max cuff pressure	300 mmHg	300 mmHg	Identical
Materials	PC and ABS for the case and plastic foil for the labels of the device. Biocompatible materials are used for the applied parts (cuff).	PC for the case and plastic foil for the labels of the device. Biocompatible materials are used for the applied parts (cuff).	Equivalent The change of the material formulation to increase the durability of the device is documented. The changed materials are not in contact with the body of the patient.

Characteristic	Subject device TONOPORT VI		Primary predicate device TONOPORT V (510(k) -No.: K012647)		Explanation of the differences
Environmental conditions for operation	Temperature	+5 to +40 °C	Temperature	+10 to +40 °C	Equivalent The environmental conditions are changed according to the requirements of the standards IEC 80601-2-30 and 60601-1-11. These changes do not affect the indications for use.
	Humidity	15 to 93 %	Humidity	30 to 75 %	
	Atmospheric pressure	700 to 1060 hPa	Atmospheric pressure	700 to 1060 hPa	
Environmental conditions for transport and storage	Temperature	-25 to +70 °C	Temperature	-20 to +70 °C	
	Humidity	10 to 93 %	Humidity	10 to 90 %	
	Atmospheric pressure	500 to 1060 hPa	Atmospheric pressure	500 to 1060 hPa	
Safety	Increased safety An additional pressure sensor and a pressure release valve are added. Two controllers (main and supervisor controller) that monitor each other and the safety related components are used.		Standard safety One pressure sensor and one valve for the deflation of the cuff are used. One controller (main controller) is used.		Equivalent The improvement of the safety properties of the device is documented.
Sterilization	Not applicable		Not applicable		Identical
Expiration date	Not applicable		Not applicable		Identical

PAR Medizintechnik GmbH & Co. KG	*Special 510(k) TONOPORT VI*

5.4 Summary of performance testing

Table 6: Performance testing to demonstrate equivalence

Characteristic	Standard/Test/FDA Guidance	Result
Safety (electrical, mechanical, chemical, thermal and radiation) and essential performance	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	Pass Pass Pass
Usability	IEC 60601-1-6	Pass
Software	IEC 62304	Pass
Risk Management		
Risk analysis	ISO 14971	Pass

The TONOPORT VI complies with the voluntary and mandatory standards. The following quality assurance measures were applied to the development of the TONOPORT VI to ensure that design inputs, safety requirements, new features, pre-existing requirements were met and re-tested:

- Requirements specification review
- Software and hardware testing
- Safety testing
- Environmental testing
- Final verification and validation
- Compliance with performance standards

An assessment of clinical data to show safety and performance of the device was not made, because the TONOPORT VI uses identical algorithms for the blood pressure measurement like the predicate device TONOPORT V. Consequently the form FDA-3674 ‘Certification of compliance with requirements of ClinicalTrails.gov data bank’ is not completed and submitted.

5.5 Conclusion

The TONOPORT VI is substantially equivalent to the TONOPORT V with respect to the indications for use and the basic scientific concept.