May 16, 2019

I.E.M. Industrielle Entwicklung and Medizintechnik
Hella Witt
Regulatory Affairs
Vertriebsgesellschaft mbH
Cockerillstrabe 69
Stolberg, 52222 DE

Re: K173895
Trade/Device Name: Tel-O-Graph
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 12, 2019
Received: April 17, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Matthew Hillebrenner
Director (Acting)
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number
K173895

Device Name
Tel-O-Graph

Indications for Use *(Describe)*

The Tel-O-Graph is intended for the home measurement of blood pressure and pulse on the upper arm in adults. The blood pressure monitor is suitable for individuals with an arm circumference of 20-55 cm (7.9-21.7 in) when used with the corresponding monitor cuff size.

The data measured is automatically transmitted.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k)	**Tel-O-Graph** **Section 05: 510(k) Summary**	

Section 05: 510(k) Summary

Submission Sponsor and Correspondent

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FDA Establishment Registration # 9617476

Date prepared: 10 April 2019

Device identification

Trade Name	Tel-O-Graph
Common name:	Self Blood Pressure Monitor
Classification Regulation:	CFR 870.1130
Classification Name	Noninvasive blood pressure measurement system
Product Code:	DXN
Device Class:	Class II
Classification Panel:	Cardiovascular

Legally Marketed Predicate Device

K041313 Stabil-O-Graph

Device Description

The Tel-O-Graph is a table-top device for upper arm blood pressure measurements. The device employs the oscillometric principle for the non-invasive determination of the blood pressure from pressure signals obtained from the pressurized cuff placed around the upper arm. The device is

operated via a single button to initiate blood pressure measurements. Data is transmitted automatically. The device is used by patients in a home environment.

Summary of technical data:

Specification	**Value**	**Unit**
Measuring method	Oscillometric	
Blood pressure measurement range	30 to 290 Systolic: 60 – 290 Diastolic:30 – 195	mmHg
Pulse measurement range	30 to 240	1/min
Pressure accuracy	±3	mmHg
Pulse rate accuracy	±2% or ±3 bpm (whichever is greater)	1/min
Memory	350	measurements
Power supply	6V (4x AA, 1.5V, alkaline)	
Dimensions (L x W x H)	152x 110 x 57	mm
Weight (excluding batteries)	325	g
Material housing	ABS (acrylonitrile-butadiene-styrene)	
Material cuff	Polyester	
Expected service BP monitor	5	years
Expected service life of the cuff	6	months
Operating temperature	+5 to +40	°C
Ambient pressure	700 to 1060	hPa
Transport and storage temperature	-25 to +70	°C
Humidity, not condensing (operation, transport and storage)	15 to 93	%
Battery capacity	c. 500	measurements
Transmission time	c. 5	min
Data connection (depending on variant)	Bluetooth or Mobile communication network	
Data transmission (depending on variant)	Class 1 Bluetooth or GPRS Class 12	

Table 5A: Summary of technical data

Accessories

Blood pressure cuffs are available in four cuff sizes:

Cuff size	Arm circumference in cm/inch
S	20 – 24 cm /7.9 – 9.5 in
M	24 – 32 cm / 9.5 – 12.6 in
L	32 – 38 cm/ 12.6 – 15.0 in
XL	38 – 55 cm / 15.0 – 21.7 in

Table 5B: Accessories

Indications for Use:

The Tel-O-Graph is intended for the home measurement of blood pressure and pulse on the upper arm in adults. The blood pressure monitor is suitable for individuals with an arm circumference of 20-55 cm (7.9-21.7 in) when used with the corresponding monitor cuff size.

The data measured is automatically transmitted.

Traditional 510(k)	**Tel-O-Graph** **Section 05: 510(k) Summary**	

Device Comparison Summary

	Stabil-O-Graph (predicate)	**Tel-O-Graph** (candidate)	Comparison of equivalence / differences
510(k) Number	K041313	K173895	same
Manufacturer	IEM GmbH	IEM GmbH	same
Classification	Class II	Class II	same
Classification Name	870.1130 Noninvasive blood pressure measurement system.	870.1130 Noninvasive blood pressure measurement system.	same
Product Code	DXN	DXN	same
Indications for Use	The Stabil-O-Graph is intended to be used by adults at home to monitor Blood Pressure (systolic and diastolic) and pulse rate from the upper arm with arm circumference ranging from 9.4 inches to 16.5 inches (24 cm to 42 cm)	The Tel-O-Graph is intended for the home measurement of blood pressure and pulse on the upper arm in adults. The blood pressure monitor is suitable for individuals with an arm circumference of 20-55 cm (7.9-21.7 in) when used with the corresponding monitor cuff size. The data measured is automatically transmitted.	Equivalent
Variants	Stabil-O-Graph mobil	Tel-O-Graph BT / GSM	Equivalent, difference only in data transmission
Principle of operation/ measurement	Oscillometric	Oscillometric	Same
Measurement range	Systolic: 70 – 260 mmHg Diastolic:45 – 180 mmHg Pulse: 40-240 bpm	Systolic: 60 – 290 mmHg Diastolic:30 – 195 mmHg Pulse: 30-240 bpm	Equivalent
Accuracy BP measurement	± 3 mmHg	± 3 mmHg	Equivalent
Memory	50 blood pressure measurements	350 blood pressure measurements	Equivalent Tel-O-Graph automatically transmits the measured data. Memory is only backup in case of transmission problems
User interaction	2 buttons: “START/STOP” and “MENU”	1 button	
Dimension and weight	Casing dimensions: 125 x 131 x 51 mm , Weight. approx. 270 g including batteries	Casing dimensions: 152 x 110 x 57mm, Weight: approx. 325 g excluding batteries	Equivalent: Differences in design of housing are not affecting safety or performance.
Materials	Casing: ABS Display: LCD	Casing: ABS Display: LCD	Equivalent

Traditional 510(k)	**Tel-O-Graph** **Section 05: 510(k) Summary**	

	Stabil-O-Graph (predicate)	**Tel-O-Graph** (candidate)	Comparison of equivalence / differences
Accessories: cuffs	Material: Polyester Textile sheath Bladder: TPU Tube: PVC Cuffs in 2 different sizes 24-32cm 32-38cm	Material: Polyester Textile sheath Bladder: TPU Tube: PVC Cuffs in 4 different sizes: 20-24cm 24-32cm 32-38cm 38-55cm	Equivalent Same materials used The additional cuff sizes do not affect the safety of the device; clinical validation covers all cuff sizes
Power supply	2 alkaline 1.5 V batteries (AA)	4 alkaline 1.5 V batteries (AA)	Equivalent Both are battery operated devices.
Biocompati-bility	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Equivalent Testing updated according to current standards
Environmental conditions	Operating conditions: +10°C to +40°C) Storage environment: -20°C to 50°C 15% to 95%rH	Operating conditions: +5°C to +40°C Storage environment: -25 °C to 70 °C 15% to 93% rH	Equivalent
Data transmission	Infrared, Bluetooth	Bluetooth, GSM	Equivalent: All are open digital technologies for data transmission; Infrared is considered as not being state-of-the-art any more

Table 5C: Device technical comparison with predicate device

Data transmission via mobile-network communication (Tel-O-Graph GSM) is considered equivalent to data transmission with the FDA cleared AM3 GSM (K13722).

	Spirometer Asthma Monitor AM3 GSM (reference)	Tel-O-Graph GSM (candidate)	Comparison
	K133722	K173895	
Transmission	Serial (RS232), USB, Bluetooth, GSM	Bluetooth, GSM	Equivalent in terms of BT and GSM transmission. Serial and USB are not wireless.
EMC testing	Done with whole device	Done with whole device (Tel-O-Graph GSM)	Equivalent

Data stored and transmitted	Result of measurement (always with date and time)	Result of measurement together with date and time	Equivalent
GSM Interface	Sierra Wireless WISMO288 GSM module	Cinterion ESH 6 GSM module	Equivalent Both modules use techniques to guarantee the integrity of the transferred data.
GSM reception	No critical data transmitted Data stored in nonvolatile memory	No critical data transmitted Storage of up to 350 measurements	Equivalent Transmission not time critical
Time point of GSM data transfer	Off-line	After measurement	Equivalent Device performance not affected through GSM function

Substantial Equivalence Discussion

IEM considers the Tel-O-Graph and its accessories as substantially equivalent to the predicate device Stabil-O-Graph.

The validation of two additional cuff sizes permits the use of the device in patients with arm circumferences of 20-55 cm. The intended use and user group are the same.
The Tel-O-Graph has an advanced method for data transmission as compared to the predicate device. Wireless data transmission was expanded to enable data transmission via the mobile network (variant Tel-O-Graph GSM). The GSM transmission is equivalent to the data transmission of the FDA cleared device Asthma Monitor AM3 GSM (K133722).

The differences between the Tel-O-Graph and the predicate device do not concern the operating principle and fundamental scientific technology. The device under application is as safe and effective as the predicate device, hence the Tel-O-Graph and the predicate device are substantially equivalent.

Nonclinical and clinical testing

Electrical safety and performance testing of the Tel-O-Graph was conducted by an external test laboratory to demonstrate conformance with recognized standards.

Bench testing confirmed compliance with:

- IEC 60601-1: 2012 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance;
- IEC 80601-2-30: 2009 Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (see exhibit 17G) The Tel-O-Graph meets the stated requirements for overall design, performance, biocompatibility, electrical safety and electromagnetic compatibility.
- IEC 60601-1-2: 2014 Medical electrical equipment; Part 1: 2. General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – requirements and tests [Recognition Number 19-08]

The device passed all testing in accordance with the applicable voluntary international standards.

Biocompatibility testing focused on the blood pressure cuff (textile sheath and tube), as other materials, i.e. the ABS plastic of the casing, have a sufficient long history of use in this configuration. Based on risk analysis and in compliance with ISO 10993-1, IEM conducted Biocompatibility testing in accordance with the following voluntary standards:

- ISO 10993-1: 2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process [Recognition Number 2-220],
- ISO 10993-5: 2009, Biological Evaluation of Medical Devices – Part 5: Tests for in-vitro cytotoxicity [Recognition Number 2-245],
- ISO 10993-10: 2010, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization [Recognition Number 2-174].

All tests were passed successfully. No relevant cytotoxic effect, sensitizing property or skin irritation was detected.

Clinical performance testing of the Tel-O-Graph covers the Tel-O-Graph monitor and its accessories. The accuracy of blood pressure measurements was tested in accordance with the same arm sequential method described in section 5.2.4.2 of ISO 81060-2: 2013 – Non-invasive sphygmomanometers -- Part 2: Clinical validation of automated measurement type.

The clinical validation of the measurement accuracy demonstrated appropriate measurement accuracy of the Tel-O-Graph according to ISO 81060-2:2013.

Conclusion

From Risk Assessment and from non-clinical and clinical device testing IEM concludes that the Tel-O-Graph device performs as well and is as save and effective as the predicate device. Performance testing confirms that product specifications are met in accordance with the technological characteristics and the intended use.