RGB Medical Devices SA
Ricardo Ruiz
Regulatory Affairs Manager
Calle de Alfonso Gomez 42
Madrid, Spain, 28037

Re: K181894
Trade/Device Name: TOF-Cuff Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, KOI
Dated: April 9, 2019
Received: April 12, 2019

Dear Ricardo Ruiz:

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 Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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 *(if known)*
K181894

Device Name
TOF-CUFF monitor

Indications for Use *(Describe)*
TOF-CUFF monitor is a device intended to monitor neuromuscular transmission and non-invasive blood pressure of adult patients during surgery and issue alarms related with these physiological parameters. It is not a therapeutic device.
The monitor should be used exclusively in health institutions by trained medical professionals. The monitor is suitable for use in the presence of electrosurgery. Monitor is not intended to be used in the home environment.
The monitor should be used only with a single patient.

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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K181894

VOLUME 006

510(k) Summary

DATE OF PREPARATION: APRIL 9, 2019

APPLICANT:

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1 Device Name

Trade Name:	*TOF-Cuff monitor*
Device Classification Name:	*Noninvasive blood pressure measurement system*
Classification Class:	*II*
Primary Product Code:	*DXN*
Regulation:	*21 CFR 870.1130*
Review Panel:	*Cardiovascular*

2 Secondary Product Code

Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Electrical peripheral nerve stimulator	Anesthesiology	Anesthesiology	KOI	868.2775	II

3 Predicate Devices / Reference Device

Device	Predicate / Reference	510(k)
BP100A Shenzhen Combei Technology Co., Ltd.	Primary predicate device	K181104
TwitchView System Blink Device Company	Secondary predicate device	K172843
CARESCAPE B450 General Electric Finland Oy.	Reference device	K132533

4 Device Description

The device consists of the TOF-Cuff monitor and the TOF-Cuff pressure cuff. The applied part of the device is the TOF-Cuff pressure cuff.

TOF-CUFF monitors the neuromuscular transmission (NMT) using the patented TOF-Cuff® method.

TOF-Cuff® is a new method of monitoring neuromuscular blockade that has several advantages over previous methods. It is based on a modified pressure cuff that incorporates stimulating electrodes. The evoked muscle response is evaluated through the changes in pressure of the cuff generated by the muscular reaction after the electrical stimulus. The modified pressure cuff is also used for NIBP (Non-invasive Blood Pressure) measurement. Thus it is possible to monitor both parameters with only one patient sensor.

NMT can work either in manual or automatic modes. In manual mode the user starts a measurement by touching buttons of main menu. In automatic mode the measurement is performed at regular intervals. The time interval between measurements is selectable by the user. In automatic mode the user can start a measurement at any time. The user can stop a NMT measurement at any moment by pressing the NMT Stop key.

TOF-CUFF monitor offers the possibility to start an automatic procedure for Neuromuscular Blockade (NMB) monitoring during the complete surgical process. The Auto-Pilot Program is designed to facilitate the work of the anaesthesiologist and change pattern type and stimulation cycle according to the different blockade phases during surgery, but NMT monitoring requires adequate vigilance and supervision by the anaesthesiologist

TOF-CUFF monitor provides systolic, diastolic and mean arterial pressure values, as well as the pulse rate, in a non-invasive way, by means of an enhanced version of the oscillometric method. The validation has been performed using as reference the intra-arterial pressure measurement

NIBP can work either in manual or automatic modes. In manual mode a measurement is performed only when Start/Stop NIBP key is pressed. In automatic mode, the measurement is performed at regular intervals. The time interval between measurements is selectable by the user. In automatic mode the user can start a measurement at any time by pressing the Start/Stop NIBP key and the next measurement would start once the selected time interval has elapsed. If Start/Stop NIBP key is pressed while a NIBP measurement is in progress, the process is stopped and the cuff deflated. During the measurement a button is also shown in the main menu area that, when pressed, stops the process.

5 Intended Use

TOF-CUFF monitor is a device intended to monitor neuromuscular transmission and non-invasive blood pressure of adult patients during surgery and issue alarms related with these physiological parameters. It is not a therapeutic device.

The monitor should be used exclusively in health institutions by trained medical professionals. The monitor is suitable for use in the presence of electrosurgery. Monitor is not intended to be used in the home environment.

The monitor should be used only with a single patient. The monitor is intended for Adult patients.

6 Comparison of Technological Characteristics

A comparison of technological characteristics of the TOF-Cuff monitor to the predicate and reference device was conducted.

6.1 Device Characteristics Table

Company	**RGB Medical Devices (New Device)**	**BP100A (Predicate Device) K181104**	**TwitchView System (Predicate Device) K172843**	**Carescape B450 (Reference Device) K132533**
Device Name	TOF-Cuff monitor	BP100A	TwitchView System	Carescape B450
Regulation Number	870.1130	870.1130	868.2775	870.1025
Class	2	2	2	2
Product Code	DXN KOI	DXN	KOI	MHX, BZK, BZL, BZQ, CAP, CBQ, CBR, CBS, CCK, CCL, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, **DXN**, FLL, GWJ, GWQ, **KOI**, KRB, MLD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
510(k) number	K181894	K181104	K172843	K132533

Indication for Use	TOF-Cuff monitor is a device intended to monitor neuromuscular transmission and non-invasive blood pressure of adult patients during surgery and issue alarms related with these physiological parameters. It is not a therapeutic device. The monitor should be used exclusively in health institutions by trained medical professionals. The monitor is suitable for use in the presence of electrosurgery. Monitor is not intended to be used in the home environment. The monitor should be used only with a single patient.	The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm). The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings. The Subject device is not intended to be diagnostic device.	The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography	The CARESCAPE Monitor B450 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility. The CARESCAPE Monitor B450 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE Monitor B450 is indicated for monitoring of: • hemodynamic (including ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output (thermodilution and pulse contour), temperature, mixed venous oxygen saturation and central venous oxygen saturation), • respiratory (impedance respiration, airway gases (CO2, O2, N2O and anesthetic agents), and spirometry) • neurophysiological status (including electroencephalography, Entropy, Bispectral Index (BIS) and neuromuscular transmission). The CARESCAPE Monitor B450 also provides alarms,

Company	RGB Medical Devices (New Device)	BP100A (Predicate Device) K181104	TwitchView System (Predicate Device) K172843	Carescape B450 (Reference Device) K132533
				trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices The CARESCAPE Monitor B450 is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.
Pattern Types	ST - Single Twitch TOF - Train of Four PTC - Post-Tetanic Count	---	ST - Single Twitch TOF - Train of Four PTC - Post-Tetanic Count Tetanic stimulation	ST - Single Twitch TOF - Train of Four PTC - Post-Tetanic Count DBS - Double Burst Stimulation Tetanic stimulation
ST cycles [s]	1, 10	---	---	1, 10, 20
TOF cycles	12 s, 30 s, 1 min, 2 min, 5 min ,10 min, 15 min, 30 min, 60 min	---	---	10 s, 12 s, 15 s, 20 s, 1 min, 5 min, 15 min
PTC tetanic period [s]	5	---	5	5
Measurement modes	Automatic and manual	---	Automatic and manual	Automatic and manual
Stimulation current range [mA]	1-60	---	10-80	1-70
Systolic pressure range [mmHg]	30 to 250	30 to 280	---	30 to 260
Diastolic pressure range [mmHg]	10 to 218	30 to 280	---	25 to 220
Mean pressure range [mmHg]	20 to 234	---	---	25 to 260

Company	RGB Medical Devices (New Device)	BP100A (Predicate Device) K181104	TwitchView System (Predicate Device) K172843	Carescape B450 (Reference Device) K132533
Physical Dimensions **Width [cm]** **Height [cm]** **Depth [cm]** **Weight [kg]**	 22.2 20.5 8 1.5	 9.2 6.1 12.8 0.49 (including battery)	 ---	 30.0 29.0 16.0 5.0
Power Supply	TOFCUFF is powered from AC mains supply. 100 – 240 VAC, 50 / 60 Hz, 0.4 - 0.22 A TOFCUFF includes an internal Li-Ion battery as secondary power supply. 11.1 V – 2.60 Ah	4- Type “AA” alkaline batteries	External AC Adapters Li-Ion battery	100 – 240 VAC, 50 / 60 Hz, 1.8 – 0.8 A Li-Ion battery 10.8 V – 3.80 Ah (optionally it can include a second battery
User Interface	TOFCUFF includes a TFT color display with the following specifications: Display size: 15.5 cm x 9.3 cm Display resolution: 800 x 480 pixels User inputs are done through a resistive touch panel and it includes a membrane keyboard with four keys for some functions (Switching on/off the device, Start/Stop NIBP measurement, Stop NMT measurement and Exit).	BP100A includes a custom design LCD with numerical presentation of data and specific symbols integrated. Three specific keys for some functions (On/Off, Setting&Time, Memory).	TFT color display Resistive touch panel and one specific key for switching on/off the device	TFT color display Resistive touch panel and one specific key for switching on/off the device
Sterilization	non-sterile	non-sterile	non-sterile	non-sterile

6.2 Conclusion of Comparison of Technological Characteristics

Each of the two vital signs monitored by the TOF-Cuff (NIBP, NMT), are also monitored by the selected predicate devices. In addition, the reference device CARESCAPE B450 can monitor several vital signs including neuromuscular transmission (NMT) and non-invasive blood pressure (NIBP), which are the two vital signs monitored by the TOF-Cuff.

The maximum NIBP measurement time specified for the TOF-CUFF monitor is below the maximum limit allowed by the requirement 201.104 of the IEC 80601-2-30. The device is in compliance with current FDA recognized standard, therefore this difference does not raise any different questions of safety or effectiveness of the device.

The technological characteristics of the TOF-Cuff monitor are substantially equivalent to the technological characteristics of the chosen predicates and reference device. There are no differences between the devices which may raise different questions of safety or effectiveness.

7 Performance Data

Non-clinical and clinical testing has been performed showing that the device performs as intended and is substantially equivalent to the primary predicate device (K181104), the secondary predicate device (K172843).

7.1 Biocompatibility

An evaluation of biocompatibility according ISO 10993-1 was performed. Furthermore biological tests according ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation) were performed to demonstrate the biocompatibility of the device.

7.2 Electrical Safety and Electromagnetic Compatibility

Electrical safety and EMC testing were conducted. The TOF-Cuff monitor is in compliance with IEC 60601-1, IEC 60601-1-6, IEC 62366, IEC 60601-1-8, IEC 60601-2-10, IEC 80601-2-30 as well as IEC 60601-1-2.

7.3 Software Verification and Validation Testing

Software verification and validation was conducted and the necessary software documentation according to the defined level of concern was provided.

The TOF-Cuff monitor provides different parameters that the user can select to set the operating mode of the device. The right operation of these parameters has been tested during the design & development process.

7.4 Clinical Testing

Two clinical investigations were performed on the TOF-cuff monitor.

The general objective of the first study was to determine the capacity of the TOF-cuff monitor of monitoring with the same device the non-invasive arterial pressure and the level of neuromuscular blockade induced with relaxant drugs.

The main objective of the second study is to compare the values of neuromuscular blockade measured with the TOF-CUFF monitor with neuromuscular blockade values measured with the CARESCAPE B450 monitor during the pharmacologically induced NMB and evaluate the degree of equivalence.

Both studies showed that the TOF-Cuff monitor supports the determination of substantial equivalence regarding its intended use.

8 Substantial Equivalence Summary / Conclusion

Based on the provided information and performed clinical and non-clinical testing our device the TOF-Cuff monitor is substantially equivalent to the primary predicate device BP100A, the secondary predicate device TwitchView System and to the reference device Carescape B450 in terms of indication for use, technology and performance specifications. There are no differences between the devices which may raise different questions of safety or effectiveness.