DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 16, 2017

Terumo BCT, Inc.
Ms. Nithya Rajan
Specialist, Regulatory Affairs
10811 W. Collins Ave.
Lakewood, Colorado 80215

Re: K162365
Trade/Device Name: T-Cuff
Regulation Number: 21 CFR 878.5910
Regulation Name: Pneumatic tourniquet
Regulatory Class: Class I
Product Code: KCY
Dated: January 16, 2017
Received: January 17, 2017

Dear Ms. Rajan:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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

Section 4, 2

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

510(k) Number *(if known)*
K162365

Device Name
T-Cuff

Indications for Use *(Describe)*
T-Cuff is indicated for use in donor populations during apheresis procedures as an alternative method to maintain pressure on the arm and obtain venipuncture. The T-Cuff operates similar to a pneumatic tourniquet intended to partially restrict blood flow on the upper arm to result in optimal venous access during apheresis collection procedures.

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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TERUMOBCT

510(k) Summary

I. SUBMITTER

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Date Prepared: February 16, 2017

II. DEVICE

Trade Name of Device: T-Cuff®
Common or Usual Name: Inflatable tourniquet
Classification Name: Pneumatic tourniquet
Regulatory Class: In accordance with 21 CFR 878.5910 the classification for this device is Class I medical device
Product Code: KCY

III. PREDICATE DEVICE

Table 1: Predicate Device Information

Device	Product Classification	Trade Name Of Predicate Device	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	KCY	EZ Vein inflatable tourniquet	Dominion Medical Devices, LLC	K112874

IV. DEVICE DESCRIPTION

A. Device Identification

The T-Cuff is a pneumatic tourniquet used as an alternative method to maintain consistent pressure on the arm and blood flow at the access site during apheresis procedures. This device is composed of 4 major components and was developed to enhance venous access during venipuncture and help donors maintain a consistent pressure on the arm during apheresis procedures. The catalog number for the T-Cuff is 71252.

B. Device Characteristics

T-Cuff is designed to maintain a consistent pressure when applied to the donor's bicep with consistent squeezing of the inflatable bulb. During the apheresis process, the device operates in two modes: Venipuncture and Collection. The mode of operation is changed by adjusting the pressure relief valve cap. During Venipuncture mode, application of T-Cuff to the donor's upper arm prior to obtaining venipuncture allows the T-Cuff to inflate to assist with vein selection. During Collection mode, the T-Cuff maintains a consistent pressure of 20-40 mmHg (millimeter

of mercury) on the donor's upper arm to help facilitate optimal blood flow during apheresis procedures. T-Cuff is a non-sterile, non-single use device.

C. **Device Description**

The T-Cuff is a pneumatic tourniquet used as an alternative method to maintain pressure on the arm and, aid in the facilitation of blood flow during apheresis procedures. It operates in two modes, Venipuncture and Collection. During Venipuncture mode, the T-Cuff is inflated to higher pressure (no greater than 120 mmHg) as venipuncture is performed. Once Venipuncture is complete, the device maintains a steady, lower, consistent pressure (20 – 40 mmHg) during Collection mode. The donor squeezes a rubber bulb in continuous intervals to distribute air through the system and, facilitate optimal blood flow during apheresis procedures. The T-Cuff does not contain an energy source. Primary mechanism of action is obtained through the influx of air into the system and, by a modulating pressure relief valve that maintains defined pressure ranges.

D. **Environment of Use**

The T-Cuff is intended for use in a blood banking environment or other similar facility. The operation of T-Cuff is performed by trained operators who manage the collection of blood products on apheresis devices. Operators of the T-Cuff have a variety of backgrounds and professional training. Primary users are expected to be nurses or qualified laboratory technicians who manage the apheresis process.

E. **Materials of Use**

T-Cuff does not come into contact with blood or other bodily fluids. The device is applied at the start of the apheresis procedure to un-broken, intact skin and, comprised of a polyurethane bladder encased in a cotton/polyester sheath. The bulb squeezed by the operator/donor is made of PVC and the tube connecting the bulb to the bladder is a non-latex EPDM. The contact surface of the pressure relief valve is stainless steel.

F. **Key Performance Specifications/Characteristics of the Device**

The pressure relief valve regulates air pressure within the system and is mechanically controlled through the two operation modes. As the inflatable bulb is squeezed by the donor, air is pushed through the rubber tubing into the pressure relief valve. As pressure gradually builds within the system; the plunger within the relief valve compresses springs based on the operation mode. This allows for air to escape through the top of the pressure relief valve and, ensures a consistent pressure range is maintained based on the operation mode of the device.

V. INDICATIONS FOR USE

T-Cuff is indicated for use in donor populations during apheresis procedures as an alternative method to maintain pressure on the arm and obtain venipuncture. The T-Cuff operates similar to a pneumatic tourniquet intended to partially restrict blood flow on the upper arm to result in optimal venous access during apheresis collection procedures.

VI. TECHNOLOGICAL COMPARISON

Control of air pressure within the device is the technological principle for both the proposed and predicate devices. It is based on limiting pressure exerted on the donor's upper arm. The subject and predicate devices are based on the same technological elements as described below:

- Squeeze bulb to circulate air within the system.
- Pressure control valve to regulate and maintain a certain pressure level within the device.
- Inflatable cuff that compresses donor's forearm or bicep to gently restrict blood flow and increase venous pressure.

The following technological differences exist between the subject and predicate devices:

- The predicate device delivers one pressure mode while the proposed device offers two pressure modes.
- The predicate device is primarily used for enhanced presentation of veins for access with a hypodermic needle while the proposed device allows for use during both venipuncture and apheresis collections.

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

A. Biocompability Testing

The biocompatibility evaluation for the T-Cuff device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization
- USP Physico-chemical tests

B. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

T-Cuff does not contain any electromechanical components and thus did not require EMC testing.

C. Software Verification and Validation Testing

The T-Cuff does not contain any software, therefore, software verification and validation testing was not performed.

D. Sterility Testing

T-Cuff is a non-sterile device; therefore sterility testing was not performed

E. Stability/Shelf Life Testing

The Pressure relief valve has been tested to be functional for a 3 year (3,000 apheresis procedure) shelf life. The cuff bladder was tested to be functional for a 1 year shelf life at which point, the customer has the option to replace the bladder component on an as-needed basis. Due

to the low likelihood of time-dependent product degradation, a specific shelf-life time frame is not applicable.

F. **Clinical Studies**

The design was validated through an IRB approved, prospective study on the Trima Accel® Automated Blood Collection system.The primary endpoint for this study was to determine if manual and/or automatic adjustments to the draw flow rate would decrease the number of operator interventions and overall procedure time. The T-Cuff was utilized for all donations in this study, and it was demonstrated that manual and automatic adjustment to the draw flow rate decreased the number of operator interventions and did not increase the overall procedure time. All products collected met the FDA regulations regarding the level of residual white blood cells ($< 5.0 \times 10^6$) and platelet yield ($\geq 3.0 \times 10^{11}$). There was also no reduction in the quantity (volume and yield) or the quality (residual white blood cells) of products collected compared to historical controls. No reported AE's were attributed to the T-Cuff.

VIII. CONCLUSIONS

Based on data collected and analyzed during Bench and Clinical testing, the T-Cuff has demonstrated to be substantially equivalent to the predicate device.