March 03, 2023

Compression Works Inc
c/o Trey Thorsen, President
O'Connell & Myers, LLC
2020 Bobcat Trail
Celina, Texas 75009

Re: K221661
Trade/Device Name: Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S)
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 30, 2023
Received: January 30, 2023

Dear Trey Thorsen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rohini Retarekar -S

for Katherine Trivedi
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221661

Device Name
Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S)

Indications for Use *(Describe)*
The Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S) is indicated for use to control bleeding in the pelvis, inguinal area, axilla and for pelvic fracture stabilization.

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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K221661

Section 5 -510(k) Summary for Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S)

Date:	February 17, 2023
510(k) Owner/Sponsor:	**Compression Works**
Address:	1634-A Montgomery Hwy #115
	Hoover, AL 35216
Establishment Number:	3009164961
Telephone Number:	205-202-1136
Contact Person:	Trey Thorsen
Telephone Number:	850-450-3932
Email Address:	trey@oconnellmyers.com

Proposed Device:	**Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S)**
Device Common Name:	Vascular Clamp
Product Code:	DXC
FDA Regulation Number:	21 CFR 870.4450
Device Classification:	Class II

Predicate Device: Abdominal Aortic and Junctional Tourniquet (K133029)

Device Common Name:	Wound Dressing
Product Code:	DXC
FDA Regulation Number:	21 CFR 870.4450
Device Classification:	Class II

Reference Device: SAM Junctional Tourniquet (K131561)

Device Common Name:	Wound Dressing
Product Code:	DXC
FDA Regulation Number:	21 CFR 870.4450
Device Classification:	Class II

5.1 Device Description

The AAJT-S device is a wedge-shaped bladder that when inflated pushes in on the body Over the target area of application. One of the target areas is the lower abdomen, over the umbilicus, compressing all the structures within, including the descending aorta, to achieve the physiological effects of aortic compression. The other two areas are over the inguinal region or the axilla. In these two areas the region is compressed with the wedge- shaped bladder including the major vasculature that runs through that area.

5.2 Intended Use

The AAJT-S is intended to control bleeding for up to 1 hour for abdominal use and up to 4 hours for junctional use until the patient can be transported to a health care facility for further treatment.

5.3 Indications for Use

The Abdominal Aortic and Junctional Tourniquet - Stabilized (AAJT-S) is indicated for use to control bleeding in the pelvis, inguinal area, axilla and for pelvic fracture stabilization.

5.4 Technological Comparison

The AAJT-S is similar in design and intended use to the 510(k) predicate device, AAJT (K133029). The differences between the subject device and the predicate device are listed below:

- Exchanging the windlass for a ladder strap and ratcheting buckle. This allows the user the ability to tighten the AAJT-S with one hand.
- Tightening apparatus of the belt was moved to the front of the device for application convenience.
- Addition of the "D" handle allowing for easier acquisition of the belt by gloved hands.
- Wider belt was added for stability and comfort.
- Exchanging the three separate cover pieces for one continuous piece of HDPE plastic.
- Increased wear time of 1 hour.
- Additional pelvic stability indication.

The AAJT-S is similar in design and indication for use to the 510(k) cleared reference device, SAM Junctional Tourniquet (K131561). The differences between the subject device and the reference device are listed below:

- Inflatable bladder:
  The SAM Junctional Tourniquet uses a Target Compression Device (TCD) to apply pneumatic pressure. The TCD is an inflatable cone shaped chamber that applies pressure to the target area to stop bleeding. The AAJT-S uses a wedge-shaped bladder to apply pneumatic pressure to the target area to stop bleeding.

- Slack removal:
  Once in position the SAM junctional Tourniquet uses Tourniquet uses a Windlass that is turned until the device is secured. Then the windlass is retained in place by a Velcro strap. The AAJT-S uses a ladder strap and ratcheting buckle that secures the device and does not require a Velcro retaining strap.

5.5 Non-Clinical Performance Testing:

Compression Works performed the following nonclinical performance tests:

Pressure Testing: to confirm the AAJT-S can stay inflated and maintain the same pressure over the target area for at least a 4-hour period.

- Force Testing: to evaluate the bond strength of the components bonded to the hard cover to demonstrate these components can withstand normal tensile forces during clinical use.

5.6 Biocompatibility

The AAJT-S is considered a surface device that may potentially contact intact skin for a duration of <24hrs (per the IFU the maximum duration of device use is no more than 4 hrs). The following biocompatibility testing was performed:

- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

5.7 Conclusion

The differences between the AAJT-S and the 510(k)-cleared predicates do not introduce new questions of safety or effectiveness. The performance of the AAJT-S is substantially equivalent to the performance of the predicate.