May 20, 2021

McEwen and Associates Consulting Ltd.
Julie Kerr
Consultant
207-1099 West 8th Avenue
Vancouver, BC V6H 1C3
Canada

Re: K202919
Trade/Device Name: ATS 5000 Automatic Tourniquet Instrument
Regulation Number: 21 CFR 878.5910
Regulation Name: Pneumatic Tourniquet
Regulatory Class: Class I
Product Code: KCY
Dated: September 25, 2020
Received: September 29, 2020

Dear Julie Kerr:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K202919

Device Name

ATS 5000 Automatic Tourniquet Instrument

Indications for Use *(Describe)*

The ATS 5000 Tourniquet System is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including:

Reduction of certain fractures
Kirschner wire removal
Tumor and cyst excisions
Subcutaneous fasciotomy
Nerve injuries
Tendon repair
Bone grafts
Total wrist joint replacement
Replacement of joints in the fingers
Knee joint replacements
Amputations
Replantations

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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K202919 - 510(k) Summary

Sponsor:	McEwen & Associates Consulting Ltd. 1099 West 8th Avenue Vancouver, BC, V6H 1C3
Contact Person:	Julie Kerr Project Manager Telephone: (604) 742-0600
Submission Date:	September 25, 2020
Trade Name:	ATS 5000 Automatic Tourniquet System
Common Name:	Tourniquet device
Product Code / Device:	KCY – Pneumatic Tourniquet. The applicable regulation is §878.5910 under the limitation defined by §878.9. We believe the proposed device requires 510(k) clearance as the deflation protocols, Cuff ID, and EZ LOP features falls outside the exemption classification.
Predicate Device:	Zimmer ® A.T.S. ® 4000 Automatic Tourniquet System, K123553, cleared 08/09/2013
Device Description:	The ATS 5000 is a non-sterile dual-port microprocessor controlled pneumatic tourniquet instrument intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. The ATS 5000 instrument is used in conjunction with available dual port tourniquet cuffs and hoses distributed/supplied by Zimmer Biomet Inc. A cuff is applied to a patient prior to the beginning of a procedure. Connective tubing is then attached to the cuff and then plugged into the ATS 5000 connector ports. The instrument is controlled via a touchscreen user interface.
Indications for Use:	The ATS 5000 Tourniquet System is intended to be used by perioperative nurses, surgeons, and anesthesiologists, to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including: Reduction of certain fractures, Kirschner wire removal, tumor

and cyst excisions, subcutaneous fasciotomy, nerve injuries, tendon repair, bone grafts, total wrist joint replacement, replacement of joints in the fingers, knee joint replacements, amputations, replantations.

Comparison to Predicate Device: The ATS 5000 instrument is substantially equivalent to other legally marketing tourniquet systems, specifically the Zimmer ATS 4000 Automatic Tourniquet System, in that the devices are similar in design, materials, and indications for use. A complete discussion of technological characteristics of the ATS 5000 compared to the predicate device may be found in Section 12. The below table highlights the primary technological differences that we believe

Technological Characteristics:

Feature	Discussion
Deflation Protocols	Two user-selectable deflation protocols allow the user to vary from the standard rapid deflation near the end of surgery. Cyclic Deflation: enables rapid detection and intervention for cauterization of bleeding vessels immediately prior to wound closure. Step Deflation: enables gradual cuff deflation to allow for gradual return of arterial flow. Both types of deflation protocols are achievable through manual changes to the pressure (same between the proposed and predicate devices). Automatic protocols, if selected, can simplify the perioperative workflow, and may simplify and standardize the detection and management of bleeding vessels.
Cuff ID	Barcode reader module in the instrument to scan cuff packing labels. If it is a barcode identified by the device the instrument will recognize the cuff as being one of the cuffs listed in the Instructions for Use and will display cuff details for the user to view (EZ Method enabled, dual ports, limb circumference range). New feature to further personalize tourniquet usage by taking into account specific details of recognized cuffs. Barcode reader module will scan any label, but will only display cuff details of recognized cuffs.
EZ Method to measure LOP	The EZ Method measures LOP by employing a tourniquet cuff recognized by Cuff ID to monitor arterial pulsations in an underlying limb by sensing pneumatic pressure pulsations in the cuff associated with volume changes in the limb as the cuff pressure is gradually increased. LOP is determined to be the cuff pressure at which the monitored arterial pulsations reach a certain threshold. The EZ Method is only enabled for cuffs recognized by Cuff ID. The EZ Method is a supplementary method to measure LOP, in addition to the Distal Method. The EZ Method enables the LOP measurement to be completed without the need for a Distal Sensor, thereby increasing convenience and speed and reducing disruptions of the perioperative workflow. Both methods monitor arterial pulsations to determine LOP as a cuff is gradually inflated. EZ Method and Distal Method provide equivalent measurements of LOP.

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Performance Data:	Non-Clinical Performance: During the development process of the ATS 5000, the following testing was completed: Electrical safety and Environmental testing in accordance with IEC 60601-1, 60601-1-2 and 60601-1-8; Software and device development was conducted in accordance with requirements of IEC 62304:2006 and AAMI/ANSI HE-75:2009/(R)2018; Device Usability testing was conducted in accordance with requirements of IEC 60601-1-6 and IEC 62366-1:2015; and Hardware and Software testing including validation. All tests passed according to predetermined acceptance criteria. Clinical Performance – Clinical data was not needed for this device. Conclusions: Expanded functionality which falls outside the 510(k)-exemption classification, does not require additional clinical data as the base technology safety and performance is well established. Existing literature, alongside the non-clinical performance data support the safety and performance of the proposed device.