April 20, 2020

PAVmed, Inc.
% Ms. Janice Hogan, Esq.
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K200559
Trade/Device Name: CarpX
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 3, 2020
Received: March 3, 2020

Dear Ms. Hogan:

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
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Office of Product Evaluation and Quality
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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 on last page*

510(k) Number *(if known)*

K200559

Device Name

CarpX

Indications for Use *(Describe)*

The CarpX is indicated for the minimally invasive isolation and incision/divison of ligaments, tendons, or fascia such as the transverse carpal ligament for treatment of carpal tunnel syndrome.

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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510(k) SUMMARY

PAVmed's CarpX

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: March 3, 2020

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Name of Device

CarpX

Common or Usual Name

Electrosurgical, Cutting & Coagulation & Accessories

Classification Name

21 CFR 878.4400, Class II, Product Code GEI

Predicate Devices

Predicate Device:

AM Surgical, Inc. Mountable Endoscopic Blade (K080133)

Reference Devices:

Smith & Nephew Saber ArthroWand with Integrated Cable (K030551)
Sonex Health, Inc. SX-One MicroKnife (K192873)

Intended Use / Indications for Use

The CarpX is indicated for the minimally invasive isolation and incision/division of ligaments, tendons, or fascia such as the transverse carpal ligament for treatment of carpal tunnel syndrome.

Device Description

The CarpX device is a sterile, single-use, hand-held, bipolar high frequency precision electrosurgical cutting tool. As with other electrosurgical tools, CarpX functions by passing energy controlled by the electrosurgical generator to tissue. CarpX is designed to mimic a mechanical cutting blade by delivering a short, focused burst of cutting radiofrequency (RF) energy from an electrosurgical generator along a narrow line on the target tissue. The RF energy cuts the target tissue along this line during minimally invasive surgical procedures, including the isolation and division of ligaments, tendons, and fascia such as the transverse carpal ligament (TCL) for the treatment of carpal tunnel syndrome.

CarpX consists of two integrated components: a proximal handpiece and a distal end. The proximal handpiece consists of a user interface with integrated finger switches and indicator lights, a cable to interface with the electrosurgical generator, a guidewire lumen and a balloon inflation port. The distal end consists of active and return electrodes, an inflatable balloon, a flexible shaft and an insulating electrode spacer.

Technological Characteristics

The CarpX has similar technological characteristics compared to its predicate device. Both the subject device and the predicate device are sterile, single-use, hand-held devices intended to cut tissue in confined spaces. As minimally invasive devices, they are both designed to allow smaller incisions and less tissue dissection compared to open surgery, including preservation of the fascia and soft tissues superficial to the transverse carpal ligament (TCL). Additionally, both devices are indicated for use in the treatment of carpal tunnel syndrome.

While the CarpX uses a precision RF electrosurgical cutting electrode whereas the predicate device uses a mechanical cutting blade, the CarpX is designed to mimic a mechanical cutting blade similar to other devices that use RF energy. In addition, the Saber ArthroWand reference device also employs the RF electrosurgical technology for ligament incision and division. As with CarpX, the Saber ArthroWand reference device's RF electrodes are positioned in a sesquipolar configuration with one active electrode focusing short bursts of RF cutting energy for precise tissue cutting in confined spaces. Lastly, the SX-One MicroKnife reference device incorporates the use of balloons similar to the subject device to create anatomical separation in the Carpal Tunnel space and displace critical structures away from the cutting element.

Performance Data

Testing was conducted to demonstrate that CarpX meets the functional, performance, design and safety requirements derived from a variety of design inputs. Design inputs were derived

from *Guidance for Industry and Food and Drug Administration Staff Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* (issued August 15, 2016), external standards and clinician input. Comprehensive bench tests were developed to verify design input requirements, demonstrate mechanical and system robustness, validate the user interface features, and validate the integrity of the product and packaging. This series of testing is summarized in the table below.

Summary of Design Testing

Test	Description
Design Verification	Verification of system requirements
Hardware Verification	Defined test cases and verified hardware dependent requirements for the CarpX Controller hardware
Design Validation	Validation of Intended Use
Usability	Validation of Intended Use and Instructions for Use (IFU) when used by qualified intended users
Packaging and Transit	Packaging integrity post environmental conditioning and transit simulation testing Device testing post environmental conditioning and transit simulation testing
Biocompatibility	Biocompatibility evaluation per AAMI/ANSI/ISO 10993-1:2009/(R)2013
Sterilization	Full validation using the "Overkill" approach per ANSI/AAMI/ISO 11135:2014 Annex B, confirming that the sterilization cycle and the EPCD 7.9 provided a sterility assurance level (SAL) of 10^{-6}.
Shelf Life	Accelerated aging testing for packaging and device
Software	Verification and Validation of software for moderate level of concern
EMC/Electrical Safety	Safety per 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012 and IEC 60601-2-2:2017 EMC per IEC 60601-1-2:2014

Animal Testing

The performance and usability of the CarpX device was analyzed in a porcine animal model. This study was conducted in compliance with FDA's Good Laboratory Practices (GLP), 21 CFR Part 58. Two animals were included in the GLP study and a total of 22 simulated carpal tunnel procedures were performed. Histopathology data was gathered on extracted tissues surrounding the target RF cutting regions and confirmed all tissues were normal. There were no complications or deaths associated with the test articles or treatment. All test devices in the study were successfully introduced and removed and the treatments successfully divided the target fascial tissue in the simulated carpal tunnel anatomy. Additionally, thermal characterization data showed that the highest temperature changes were immediately above the electrode indicating that worst-case temperatures are concentrated to the cutting zone. Similarly, peak temperatures greater than 45°C were limited to the surgical electrodes and

not significantly sustained. The CarpX device insertion, tunnel creation, and subsequent thermal application resulted in successful division of the target tissue fasciae located dorsal to the neurovascular structures and muscle layers in the anatomic area of treatment. Therefore, the CarpX device is substantially equivalent to the predicate device.

Cadaver Testing

Comparative use testing, usability validation, and design validation was completed on fresh or frozen fresh cadaver arms. Comparative use testing was performed to evaluate and compare the CarpX to the predicate device. Four cadaver arms were used for the CarpX and predicate endoscopic visualization as well as the identification of a transligamentous recurrent motor branch, while one cadaver arm was used for the dimensional and spatial evaluation. Using a clinically relevant model, both the predicate and CarpX device techniques allowed for easy visualization of the carpal tunnel anatomy including a simulated transligamentous recurrent motor branch of the median nerve. The CarpX visualization technique provided a 360 degree view of the carpal tunnel, while the predicate visualization technique resulted in a narrower field of view, limited to the width of the cannula opening. The CarpX creates significant distance between the median and ulnar nerves from the active cutting blade, which is greater than the 1mm maximum zone of injury of the CarpX. The results of this testing demonstrate that the CarpX is substantially equivalent to the predicate.

Usability validation testing was completed to confirm that the device can be used in accordance with its intended use and IFU when used by qualified intended users (e.g., hand surgeons) to divide the TCL in human cadaver specimens without serious use errors under expected use conditions. Five (5) surgeons performed 4 or 5 simulated carpal tunnel release procedures; a total of 23 simulated procedures were performed. The acceptance criteria for the usability validation testing are the absence of hazardous use errors during performance of critical tasks and that no serious injury to the user or simulated patient should occur during testing. The results demonstrated that the CarpX is safe and effective for the intended users, uses, and use environments. All use errors were absent during the performance of the critical tasks and no new errors were identified during testing. Finally, the TCL was successfully divided in all cases and no serious harm was observed in any of the simulated patient cadaver arms and no serious harm was observed to any of the surrounding tissue.

Design validation testing was conducted to confirm that the CarpX meets design validation requirements and that the device can be used in accordance with its intended use and IFU. Four (4) hand surgeons performed a total of 15 procedures on patient cadaver arms. All acceptance criteria were met and all testing passed the design validation requirements. Additionally, the results showed that all users on all 15 procedures performed, were able to successfully divide the TCL and no serious harm was observed in any of the simulated patient cadaver arms or surrounding tissue.

Clinical Testing

To demonstrate the safety and effectiveness of the CarpX device for the minimum invasive treatment of carpel tunnel syndrome, PAVmed has conducted a prospective, single-center, non-blinded, single-arm study in one site in New Zealand.

A total of 20 patients were enrolled in the study. Subject enrollment was based on selection criteria for inclusion and exclusion regarding demographics, medical history and clinical status. Subjects meeting criteria and providing written informed consent were treated. Two plastic surgeons performed the surgeries with CarpX. All 20 subjects completed the procedure. One subject was lost to follow-up prior to the 90-day evaluation time point.

No serious adverse event probably or definitely related to the device was observed through the 90-day follow-up period of the study. Most reported AEs were minor and expected.

The secondary endpoint of the study was clinical device technical success, defined as the ability of the CarpX to perform complete division of the transverse carpel ligament as assessed by post-procedural endoscopic inspection of the TCL after treatment. All procedures in the study were completed successfully. All ligaments were judged by endoscopic visual confirmation to be completely divided at procedure conclusion. Functional outcomes were also improved at 90 days compared to baseline.

Therefore, the clinical study showed that the treatment of CTS using CarpX was safe and effective.

Substantial Equivalence

CarpX is substantially equivalent to the predicate device, AM Surgical Mountable Endoscopic Blade (K080133). CarpX also shares similar technological characteristics as the reference devices, ArthroCare (now Smith & Nephew) Saber ArthroWand (K020557) and Sonex Health, Inc. SX-One MicroKnife (K192873). The CarpX device has the same intended use as the AM Surgical predicate device. Specifically, both devices are intended to incise and divide tissue in minimally invasive surgical procedures, including the treatment of carpal tunnel syndrome. Although the predicate device is indicated for broader use than the CarpX, including ligament release in other surgical procedures such as plantar fasciotomy for plantar fasciitis and forearm fasciotomy for compartment syndrome, its indications encompasses that of the subject device, namely, the carpal tunnel release for carpal tunnel syndrome. Thus, the indication for use of the CarpX for the incision and division of ligaments such as the TCL for treatment of carpal tunnel syndrome is very similar to the broader, already cleared uses of the predicate.

CarpX has similar technological characteristics as the predicate device. Both devices are hand-held cutting devices intended to excise tissue using a minimally invasive approach. The devices are designed to allow less soft tissue dissection, including the preservation of the superficial fascia above the ligament. Both devices are sterile, single-use devices. The primary technological difference between CarpX and the predicate device is the TCL cutting element. While the predicate device uses a mechanical cutting blade to perform the cutting function, CarpX uses a precision RF electrosurgical cutting electrode. However, this difference does not raise new questions of safety or effectiveness, as the RF cutting electrode is designed to mimic the sharp edge of a mechanical blade by focusing a very short burst of cutting RF energy along a very narrow line, allowing it to rapidly and precisely cut the target tissue along this line with no significant thermal spread.

Both CarpX and the predicate device include a component which protects critical structures during TCL cutting, including nerves located deep (median) and lateral (ulnar) to the TCL, by isolating them from the cutting element. The predicate device's protection component is a slotted cannula which isolates the critical structures from the mechanical cutting blade, which is mounted on the cannula and locked. CarpX's protection component is a balloon which positions the cutting element on the undersurface of the tensioned TCL and displaces critical structures away from the RF cutting electrode. Relatedly, the SX-One MicroKnife reference device also uses balloons in the carpal tunnel space to create anatomic separation.

In addition, the Saber ArthroWand reference device also employs this RF electrosurgical technology and this method of ligament incision and division is well-established when used to cut fibrous tissue. The reference device is available for use during arthroscopic procedures to achieve a variety of effects including tissue cutting. The distal ends of the RF electrodes have various configurations including longitudinal blade designs similar to CarpX. As with CarpX, the reference device RF electrodes are positioned in a sesquipolar configuration with one active electrode focusing short bursts of RF cutting energy for precise tissue cutting in confined spaces.

The CarpX device also has the same principles of operation compared to its predicate device. With both devices, the surgeon inserts an endoscope through a small incision into the carpal tunnel, performs an initial anatomic assessment visualizing the critical structures (including any variants) as well as the target cut line on the TCL and aborts the procedure if there are any concerns with the anatomy. The surgeon then cuts the TCL using a small cutting element (mechanical cutting blade or RF cutting electrode) while a protection component (slotted cannula or balloon) isolates and protects critical structures from the cutting element.

Conclusion

The CarpX has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the CarpX and its predicate devices raise no new or different issues of safety or effectiveness. Performance data demonstrate that the CarpX is as safe and effective as the predicate and reference devices. As such, the CarpX is substantially equivalent to its predicate device.