December 20, 2019

Sonex Health, Inc.
% Keri Ng
Consultant
Keri Ng Consulting
11 1st Ave SW
Rochester, Minnesota 55902

Re: K192873
Trade/Device Name: SX-One MicroKnife
Regulation Number: 21 CFR 888.4540
Regulation Name: Orthopedic Manual Surgical Instrument
Regulatory Class: Class I, reserved
Product Code: LXH
Dated: October 7, 2019
Received: October 8, 2019

Dear Keri Ng:

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,

Laura Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K192873

Device Name
SX-One MicroKnife

Indications for Use *(Describe)*
The SX-One MicroKnife is a disposable device intended to create space within the carpal tunnel and transect the transverse carpal ligament (TCL) for the 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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SECTION 5: 510(K) SUMMARY

Sponsor/Submitter:	Sonex Health 11 1st Avenue SW, Suite 202 Rochester, MN 55902
Contact Person:	Aaron Keenan Vice President, Operations Phone: (507) 219-1464 Fax: (507) 201-8766
Date Prepared:	December 20, 2019
Device Trade Name:	Sonex Health SX-One MicroKnife
Common Name:	Carpal Tunnel Release System
Device Classification:	Class I
Regulation Number:	21 CFR 888.4540
Classification Name:	Orthopedic Manual Surgical Instrument
Product Code:	LXH
Primary Predicate Device:	Orthomet Anatomically Guided Carpal Tunnel Release (K943873)
Reference Device:	LB Medical Inflatable Tissue Elevator/Expander System (K080158)
Device Description:	The Sonex Health SX-One MicroKnife is a mechanical device that uses a blade to manually transect the transverse carpal ligament. The device is provided sterile and intended for single use.
Device Operation:	The SX-One MicroKnife® consists of a thin stainless-steel shaft connected to a handpiece that is designed to be ambidextrous. A lever on the handle is activated to unlock the blade actuator and inflate the two balloons located on the lateral sides of the tip of the device. The blade actuator is used to activate a cutting blade that transects the TCL. The cutting blade is manually moved proximally and distally along a track. The purpose of the blade is to transect the transverse carpal ligament to treat carpal tunnel syndrome.

Indications for Use: The SX-One MicroKnife is a disposable device intended to create space within the carpal tunnel and transect the transverse carpal ligament (TCL) for the treatment of carpal tunnel syndrome

Technological Characteristics: The Sonex Health SX-One MicroKnife is designed with a blade that can transect the transverse carpal ligament to treat carpal tunnel syndrome. The subject device also utilizes balloons on the distal tip, and when inflated, increase the width of the distal tip creating space in the carpal tunnel to help move tissue away from the distal tip to assist the user during TCL transection.

Performance Data: The function of SX-One has been validated through:

- Performance Testing
- Sterilization Validation: The sterilization of the subject device was validated per ISO 11137-1:2018 (Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products) and ISO 11137-2: 2013 (Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose)
- Biocompatibility: Cytotoxicity, Sensitization, and Irritation, and Acute Systemic Toxicity was performed.
- Shelf Life: The shelf life of the subject device was substantiated by accelerated aging performance testing per ASTM F1980-16 (Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices).

Clinical Data: No clinical data was required.

Animal Data: No animal performance data was required.

Predicate Device Comparison

Attribute	**Subject Device Sonex Health SX-One MicroKnife**	**Primary Predicate Device Orthomet Anatomically Guided Carpal Tunnel Release**
510(k) number	TBD	K943873
Clearance Date	TBD	April 26, 1995
Manufacturer	Sonex Health	Orthomet
Trade Name	SX-One MicroKnife	Anatomically Guided Carpal Tunnel Release
Common Name	Carpal Tunnel Release System	Same, Carpal Tunnel Release System
Class	Class I	Same, Class I
Product Code	LXH	Same, LXH
Classification Section	888.4540	Same, 888.4540

Attribute	Subject Device Sonex Health SX-One MicroKnife	Primary Predicate Device Orthomet Anatomically Guided Carpal Tunnel Release
Indications for Use	The SX-One MicroKnife is a disposable device intended to create space within the carpal tunnel and transect the transverse carpal ligament for the treatment of carpal tunnel syndrome.	The Orthomet Anatomically Guided Carpal Tunnel Release System is intended for accessing and surgically cutting the transverse carpal ligament for the surgical treatment of carpal tunnel syndrome.
Intended Region	Wrist	Same, Wrist
Intended Use	To cut the transverse carpal ligament	Same, To cut the transverse carpal ligament
Technological Characteristics	Uses a blade to manually cut the transverse carpal ligament to treat carpal tunnel syndrome	Same, Uses a blade to manually cut the transverse carpal ligament to treat carpal tunnel syndrome
Cuts the Transverse Carpal Ligament?	Yes	Same, Yes
Clinical Benefit	To treat carpal tunnel syndrome	Same, To treat carpal tunnel syndrome
Single Use?	Yes	Same, Yes
Provided Sterile?	Yes	Same, Yes
Number of Components	Two. MicroKnife and Syringe	Three. Curved anatomic guide, nerve probe, guide knife
Ambidextrous	Yes	No. Curved anatomic guide is provided in both a right and left hand configuration
Flexible Distal Tip?	Yes	Same, Yes

Summary of Substantial Equivalence: The Sonex Health SX-One MicroKnife is substantially equivalent to the predicate device as confirmed through relevant performance tests and attributes. There are no differences between the subject and predicate device affecting the safety and effectiveness of the SX-One MicroKnife.