September 29, 2025

Sonex Health
Sara Petrie
Director of Quality Assurance and Regulatory
950 Blue Gentian Rd
Suite 200
Eagan, Minnesota 55121

Re: K252594
Trade/Device Name: UltraGuideCTR® image guided soft tissue release system
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 15, 2025
Received: August 15, 2025

Dear Ms. Petrie:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.09.29 12:29:23 -04'00'

Jesse Muir, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252594

Please provide the device trade name(s).

UltraGuideCTR® image guided soft tissue release system

Please provide your Indications for Use below.

The UltraGuideCTR® image guided soft tissue release system using real-time ultrasound visualization and guidance with integrated safety-engineered Sharps Injury Prevention is indicated for use in minimally invasive soft tissue release:

• Carpal tunnel release in the wrist

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252594

510(k) Summary

Prepared on: 2025-09-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sonex Health
Applicant Address	950 Blue Gentian Rd Suite 200 Eagan MN 55121 United States
Applicant Contact Telephone	612-396-9849
Applicant Contact	Sara Petrie
Applicant Contact Email	spetrie@sonexhealth.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	UltraGuideCTR® image guided soft tissue release system
Common Name	Arthroscope Accessory
Classification Name	Arthroscope
Regulation Number	888.1100
Product Code(s)	HRX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223406	SmartRelease® Endoscopic Soft Tissue Release System	HRX
K192873	UltraGuideCTR® (formerly SX-One MicroKnife)	LXH

Device Description Summary

21 CFR 807.92(a)(4)

The UltraGuideCTR® image guided soft tissue release system with Sharps Injury Prevention feature is comprised of a disposable Handpiece with inflatable Balloons and a Blade assembly (UltraGuideCTR® device) that is utilized with Ultrasound imaging (continuous real-time Ultrasound visualization and guidance). The device is gamma sterilized and intended for single-use only.

Continuous real-time multi-planar ultrasound imaging throughout the procedure enables the user to visually identify pertinent anatomical structures of the hand and wrist and to visualize and navigate the device throughout the procedure. The device design and components enhance the echogenicity and visualization of the device and ensures the device is compatible with any musculoskeletal (MSK) Ultrasound system. The echogenic features of the device include:

- Inflatable Balloons located along the Shaft on either side of the Blade track, which, once inflated with saline, appear under Ultrasound as two dark circles.
- Metal Shaft/Tip of Blade – the Shaft, which houses the recessed blade at the distal Tip, appears as a bright echogenic line, with a visible notch indicating the point where the recessed Blade will be deployed from the Tip of the Shaft.
- After deployment, the Blade appears on Ultrasound as a bright star-shaped structure moving along the track in the Shaft.

Collectively, these echogenic features facilitate visualization and navigation of the device within the critical anatomy throughout the procedure.

The low-profile of the Tip allows the device to be inserted through a single, percutaneous incision in the proximal wrist flexor crease. The device is operated using an ergonomic Handle with separate controls to activate and inflate the integrated Balloons and actuate the Blade. The two inflatable Balloons are integrated on either side of the Blade track in the Shaft and once inflated, function as both anatomical guards and visual confirmation of desired device placement, as well as a safety mechanism before the Blade can be deployed from the Tip.

The Balloons are inflated in the intracarpal space of the carpal tunnel to create additional space and protect the surrounding anatomy while the Blade is actuated to transect the TCL. The design of the Blade includes a safety-engineered Sharps Injury Prevention feature. The Blade remains recessed in the Tip of the device until the Balloons are inflated using the Activation Lever on the Handle. Once the Balloon inflation/Blade interlock safety mechanism is released, the Blade Slider on the Handle is pulled back in a retrograde motion to actuate the Blade in a distal-to-proximal direction along the Blade track in the Shaft to transect the TCL. The Blade must be retracted into the fully recessed position in the Shaft before the Balloons are deflated, and the device is removed.
This integrated design of the Metal Tip/Shaft/Blade and Balloons serves to protect the surrounding anatomy during the palmar pressure that is applied to the device during the insertion, navigation, TCL transection, and removal of the device, and prevents deployment of the Blade prior to inflation and subsequent to deflation of the Balloons.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The UltraGuideCTR® image guided soft tissue release system using real-time ultrasound visualization and guidance with integrated safety-engineered Sharps Injury Prevention is indicated for use in minimally invasive soft tissue release:

• Carpal tunnel release in the wrist

Indications for Use Comparison

21 CFR 807.92(a)(5)

Subject device has same indications for use as predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The UltraGuideCTR® image guided soft tissue release system and predicate device have the same intended use, indications for use, and technological elements:
• Procedure workflow;
• Use image guidance throughout the procedure to visualize pertinent anatomical structures and determine the orthopedic instrument placement prior to transecting the targeted fibro-osseous tissue (e.g., the transverse carpal ligament);
• Minimally invasive orthopedic instrument used to transect targeted fibro-osseous tissue;
• Sterile;
• Designed for ambidextrous use;
• Single use for disposable components; and
• Design elements, materials, and manufacturing items

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The device performance was verified and validated in accordance with its intended use per the planned performance tests. The following performance results support substantial equivalence determination:
o Design Basics Testing
o Distribution Simulation and Packaging Integrity Testing
o Functions and Dimensional Testing
o Hydraulic System Cycles and Rated Pressure Testing
o Challenge Loadings at Distal Tip Testing
o Sharps Injury Prevention Testing
o Cadaveric Insertion, Use, and Removal with Echogenic Guidance
o Labelling
o Human Factors Hand Tool Framework
o Usability of Device Preparation
o Usability of Device Use

o Sterilization Testing
The sterility validation of the UltraGuideCTR™ was conducted in accordance with ANSI/AAMI/ISO 11137-2. A Sterility Assurance Level (SAL) of 10-6 was achieved.

o Biocompatibility Testing
The biocompatibility evaluation was conducted in accordance with FDA recognized International Standard ISO 10993-1: 2018 Biological Evaluation of Medical Devices – Part 1: evaluation and Testing Within a Risk Management Process and in accordance with FDA guidance

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," issued September 8, 2023. The battery of testing, all conducted on final finished devices, included the following tests:

- Cytotoxicity.
- Sensitization.
- Intracutaneous Irritation.
- Materials Mediated Pyrogenicity.
- Acute Systemic Toxicity.

The subject device, Sonex Health UltraGuideCTR was evaluated to ensure that it functions in accordance with the design specifications and indications for use. Bench testing was performed on sterilized samples. The outcome of all testing was acceptable. The UltraGuideCTR is as safe, as effective, and performs as well as the predicate.