October 15, 2025

Hand Biomechanics Lab, Inc.
Egypt Brown
Quality and Regulatory Manager
77 Scripps Drive, Suite 104
Sacramento, California 95825

Re: K252020
Trade/Device Name: TunnelVision Endoscopic Soft Tissue Release System and the HBL Blade Assembly
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, KCT, EMF
Dated: September 11, 2025
Received: September 11, 2025

Dear Egypt Brown:

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2025.10.15 14:32:44 -04'00'

For: 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.	K252020

Please provide the device trade name(s).

TunnelVision Endoscopic Soft Tissue Release System; HBL Blade Assembly

Please provide your Indications for Use below.

The TunnelVision Endoscopic Soft Tissue Release System is indicated for use in minimally invasive ligament or fascia release:
Carpal tunnel release in the wrist
Cubital tunnel release in the elbow

The HBL Blade Assembly is indicated for use with the TunnelVision Endoscopic Soft Tissue Release System, the 3M Agee Inside Job Carpal Tunnel Release System, or the MicroAire SmartRelease Endoscopic Soft Tissue Release System in minimally invasive ligament or fascia release:
Carpal tunnel release in the wrist
Cubital tunnel release in the elbow

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) Summary

Owner Information: Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, CA 95825-6209
Phone: (916) 923-5073
Contact Person: Egypt Brown
Email: ebrown@handbiolab.com

Date Prepared: June 27, 2025

Device Name: Trade Name: TunnelVision Endoscopic Soft Tissue Release System; HBL Blade Assembly

Classification:
- Class II – Arthroscope, 21 CFR 888.1100 (HRX)
- Class II – Sterilization Container, 21 CFR 880.6850 (KCT)
- Class I – Manual Surgical Instruments 21 CFR 878.4800 (EMF)

Predicate Devices:
- Primary Predicate: MicroAire® SmartRelease® Endoscopic Soft Tissue Release System (K181819)
- Additional Predicate: HBL Blade Assembly, Model CTR-455 (K222490)

Device Description:
Hand Biomechanics Lab's TunnelVision Endoscopic Soft Tissue Release System is a surgical system designed for minimally invasive soft tissue release procedures. The system includes the TunnelVision Endoscope, TunnelVision Handpiece, reusable manual surgical instruments (small and medium dilators, synovium elevator, coequal dilator), an instrument sterilization tray, and the HBL Blade Assembly.

The HBL Blade Assembly (Model CTR-455) was previously cleared under 510(k) K222490 for use with the 3M® and MicroAire® SmartRelease® systems. This submission expands indications for use to include compatibility with the TunnelVision platform. No changes were made to blade assembly materials, design, or sterilization method.

Reusable components (handpiece, endoscope, surgical instruments, sterilization tray) are supplied non-sterile, to be cleaned and steam sterilized by the end user. The HBL Blade Assembly is a sterile, gamma-irradiated, single-use device.

Indications for Use:
The TunnelVision Endoscopic Soft Tissue Release System is indicated for use in minimally invasive ligament or fascia release:
- Carpal tunnel release in the wrist
- Cubital tunnel release in the elbow

The HBL Blade Assembly is indicated for use with the TunnelVision Endoscopic Soft Tissue Release System, the 3M Agee Inside Job Carpal Tunnel Release System, or the MicroAire SmartRelease Endoscopic Soft Tissue Release System in minimally invasive ligament or fascia release:
- Carpal tunnel release in the wrist
- Cubital tunnel release in the elbow

Technological Characteristics Compared to Predicate Devices:
The technological principle for both the subject and predicate devices is endoscopic soft tissue release. Both systems employ endoscopic visualization and a controlled cutting mechanism to safely

divide targeted ligamentous and fascial tissue in the wrist and elbow, thereby relieving compression of adjacent neurovascular structures.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Endoscope – provides direct visualization of the surgical field
- Handpiece – used to control and guide the cutting instrument
- Blade assembly – cutting component which divides soft tissue in a retrograde motion under direct endoscopic visualization
- Sterilization tray – used for cleaning and sterilization of reusable components
- FDA Class I manual surgical instruments – accessory tools for tissue manipulation and procedural support

The subject device is comprised of two components:

1. TunnelVision Endoscopic Soft Tissue Release System – includes the endoscope, handpiece, manual surgical instruments, and sterilization tray. These components are reusable following validated cleaning and sterilization processes.
2. HBL Blade Assembly – a gamma-sterilized, single-use disposable device containing the cutting blade. The blade cuts in a retrograde direction to safely release the targeted soft tissue.

The following characteristics are shared between the subject and predicate devices:

- Both are indicated for minimally invasive ligament release of the carpal tunnel in the wrist and fascia release of the cubital tunnel in the elbow
- Both are made from similar materials
- Both operate on the same technological principles
- Both have comparable overall design architecture
- The handpiece, endoscope, and manual surgical instruments are reusable following cleaning and sterilization in the sterilization tray
- The blade assembly is provided sterile for single use

The following technological differences exist between the subject and predicate devices:

- None. The TunnelVision Endoscopic Soft Tissue Release System (reusable set) and the HBL Blade Assembly (single-use component) are technologically identical to the predicate system, with no changes to materials, manufacturing processes, or technological characteristics.

Performance Data:
Testing to support substantial equivalence included:
- Blade retention force
- Endoscope and instrument deflection under load
- Sterilization tray durability and weight capacity
- Life cycle testing
- Packaging and transport testing
- Biocompatibility
- Sterilization and reprocessing validation
- Human factors cadaveric evaluation

Conclusion:
The TunnelVision Endoscopic Soft Tissue Release System, when used with the HBL Blade Assembly, has the same intended use and technological characteristics as the predicate devices (K181819 and K222490). There are no differences in design, materials, or performance that raise new questions of safety or effectiveness. Performance, validation, and usability testing confirm substantial equivalence.