November 14, 2022

Hand Biomechanics Lab, Inc
Dustin Dequine
CFO
77 Scripps Drive, Suite 104
Sacramento, California 95825

Re: K222490
Trade/Device Name: HBL Blade Assembly
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 17, 2022
Received: August 17, 2022

Dear Dustin Dequine:

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,

Sara S. Thompson -S

For

Laura C. Rose, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222490

Device Name
HBL Blade Assembly

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Owner Information: Hand Biomechanics Lab, Inc.
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Contact Person: Dustin Dequine
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Date Prepared: November 14, 2022

Name of Device: Trade Name: HBL Blade Assembly
Model Number: CTR-455
Common Name: Blade Assembly
Classification Name: Arthroscope [21CFR 888.1100, Product Code: HRX]
Classification: Class II

Predicate Device: MicroAire® SmartRelease® Endoscopic Soft Tissue Release System, K181819

Description of Device:

The HBL Blade Assembly is a surgical device designed to divide the ligament during an endoscopic carpal tunnel release (ECTR) or the fascia during an endoscopic cubital tunnel release (ECuTR). This device is capable of elevating a cutting blade from a retracted position within the cannula to an exposed position for cutting the ligament or fascia. Once the ligament or fascia has been divided, the cutting blade can be returned to a safe position within the cannula.

The HBL Blade Assembly is composed of a probe assembly that is fabricated using medical grade injection molded plastic, and both a spring and cutting blade that are fabricated using stainless steel. The Blade Assembly is provided sterile and designed for single use.

Indications for Use:

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

- Carpal tunnel release in the wrist
- Cubital tunnel in the elbow

Technological Characteristics Compared to Predicate Device:

The HBL Blade Assembly is comparable to the blade assembly of the predicate device with respect to technology, materials, and design. 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 use a blade activation mechanism with a spring to elevate and retract the cutting blade.

There are also minor design differences between the proposed and predicate devices. Specifically, the predicate uses a wireform but the proposed device does not. The purpose of the wireform in the predicate device is to ensure the blade retraction path is predominantly vertical. In the subject device, the curvature of the blade slot has the same effect by controlling the location of the blade. Both blade retraction methods accomplish the same predominantly vertical path and have the same functional purpose.

Both devices are made of plastic and metal components. The exact polymer and color additive, if any, is unknown for the predicate device; however, the safety and effectiveness of the proposed device materials have been demonstrated through the performance testing. Both are delivered to the customer sterile.

Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Blade Activation Mechanism Performance:

Both the predicate and subject devices are anticipated to be cycled during a typical surgical procedure. A cyclic load test verified the device is capable of exceeding typical surgical requirements without any failure or malfunction.

Cutting Blade Comparison:

Both the predicate and subject devices utilize a cutting blade to divide the ligament or fascia. A comparison of the cutting performance was performed using both devices.

Static Overload Performance:

Both the predicate and subject devices transfer load from the handpiece trigger to the blade through a pushrod. The device coupled with the predicate system were tested to ensure the device could withstand the forces that may be applied to the handpiece trigger.

Bending Stiffness Comparison:

Both the predicate and subject devices experience a bending load to the palmar surface of the blade assembly probe as the surgeon lifts the blade assembly against the deep surface of the ligament or fascia. A comparison of device stiffness was performed using both devices.

Sterilization, Packaging & Shelf Life:

The subject device is supplied sterile and is a single use device. The subject device is sterilized via gamma irradiation. The sterilization cycle has been validated to a sterility assurance level (SAL) of 10-6, in accordance with AAMI TIR 13004:2013 (R2016) Sterilization of Healthcare Products - Radiation - Substantiation of a selected dose: Method VDmaxSD.

The subject device sterile packaging was validated in accordance with the following standards as part of a study demonstrating that the packaging system is stable over its labeled shelf life:

- ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Biocompatibility:

In accordance with ANSI/AAMI/ISO 10993-1:2018, the subject device is classified as “external communicating device”, in contact with “tissue/bone/dentin” and “limited exposure” (≤ 24 hours).

Cadaveric Study:

Multiple surgeons with experience using the predicate device participated in a cadaveric study to evaluate the subject device. Study participants demonstrated the subject device can perform its intended use safely and effectively per the instructions for use.

Summary

The predicate and subject devices operate under similar technological and functional principles using similar materials. Device functional tests and a cadaveric study by multiple surgeons were

performed to evaluate the subject device for compatibility with the predicate system. All test results demonstrated the HBL Blade Assembly performs the intended use safely and effectively.