June 24, 2021

MicroAire® Surgical Instruments
Glenn Gerstenfeld
Vice President, QA/RA and Compliance Officer
3590 Grand Forks Blvd
Charlottesville, Virginia 22911

Re: K211297
Trade/Device Name: SMARTRELEASE® Endoscopic Soft Tissue Release System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, KCT, EMF
Dated: April 27, 2021
Received: April 28, 2021

Dear Glenn Gerstenfeld:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211297

Device Name
SMARTRELEASE® Endoscopic Soft Tissue Release System

Indications for Use *(Describe)*

The SMARTRELEASE® 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
- Plantar fascia release in the foot
- Gastrocnemius aponeurosis recession in the leg

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

SMARTRELEASE® Endoscopic Soft Tissue Release System

510(k) Number: K211297

1. Submission Sponsor

MicroAire® Surgical Instruments Inc.
3590 Grand Forks Blvd.
Charlottesville
VA, 22911
USA
Contact: Glenn Gerstenfeld
Title: VP, QA/RA and Compliance Officer
Phone: +1 434 975 8344

2. Date Prepared

June 24, 2021

3. Device Identification

Trade/Proprietary Name: SMARTRELEASE® Endoscopic Soft Tissue Release System
Common/Usual Name: SMARTRELEASE
Classification Name: Arthroscope
Regulation Number: 21 CFR 888.1100
Product Code: HRX, KCT, EMF
Class: Class II
Classification Panel: General & Plastic Surgery

4. Predicate Device(s)

The predicate devices for this submission are: MicroAire's SMARTRELEASE® Endoscopic Soft Tissue Release System (K181819, primary predicate device), and A.M. Surgical Mountable Endoscopic Blade (K080133, secondary predicate device). Neither of these predicates have been the subject to a design-related recall. No reference devices were used in this submission.

5. Intended Use / Indication for Use Statement

The SMARTRELEASE® 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
- Plantar fascia release in the foot

- Gastrocnemius aponeurosis recession in the leg

6. Device Description

MicroAire's SMARTRELEASE® Endoscopic Soft Tissue Release System is comprised of the following components: the SMARTRELEASE® Endoscope, the SMARTRELEASE® Handpiece, the SMARTRELEASE® Standard and Onyx Blade Assemblies. The system includes a set of Manual Surgical Instruments. The SMARTRELEASE® Handpiece, the SMARTRELEASE® Endoscope, and the Manual Surgical Instruments are reusable after cleaning and subsequent sterilization. The SMARTRELEASE® Blade Assemblies are gamma sterilized and intended for single-use only.

7. Substantial Equivalence Discussion

There have been no design changes between the originally cleared SMARTRELEASE® Endoscopic Soft Tissue Release System and the proposed device. Thus, the two SMARTRELEASE devices have the same technological characteristics as there have been no changes to the design, manufacturing, sterilization, or packaging of the device. Additionally, the proposed SMARTRELEASE® Endoscopic Soft Tissue Release System has minor differences in technological characteristics with the second predicate device, albeit same materials, blade material, and sterilization method. While the proposed Indications for Use differ between the initially cleared and proposed SMARTRELEASE device, the proposed Indications for Use is identical to the secondary predicate device. The use of Endoscopic blades in these expanded indications has been well-established and does not raise any new issues of safety and effectiveness.

8. Non-Clinical Performance Data

A User Design Validation was conducted to evaluate the safety and effectiveness of the SMARTRELEASE Endoscopic Soft Tissue Release System when used according to the indications for use. The validation involved 15 orthopedic and foot-specialist surgeons in cadaver studies for both the plantar fascia and gastrocnemius releases. Results of the Design Validation support the indications for use of the SMARTRELEASE® Endoscopic Soft Tissue Release System and that the product meets the documented User Needs for the device. The Design Validation conclusion confirms that the device is safe and effective when used according to the instructions for use.

All testing demonstrated that the SMARTRELEASE® Endoscopic Soft Tissue Release System is as safe and effective as the predicate device.

9. Statement of Substantial Equivalence

The SMARTRELEASE® Endoscopic Soft Tissue Release System has the same intended use as the A.M. Surgical Mountable Endoscopic Blade predicate device, and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the SMARTRELEASE® Endoscopic Soft Tissue Release System is as safe and effective as the predicate device. Therefore, the SMARTRELEASE® Endoscopic Soft Tissue Release System is substantially equivalent to the predicate devices.