February, 2, 2023

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

Re: K223406
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: November 4, 2022
Received: November 9, 2022

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,

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)*
K223406

Device Name
SmartRelease® Endoscopic Soft Tissue Release System

Indications for Use *(Describe)*
The MicroAire® SmartRelease® Endoscopic Soft Tissue Release System is indicated for:
• Carpal tunnel release in the wrist
• Cubital tunnel release in the elbow
• Trigger finger release in the hand

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

SmartRelease® Endoscopic Soft Tissue Release System

1. Submission Sponsor

MicroAire® Surgical Instruments, LLC
3590 Grand Forks Blvd.
Charlottesville, VA 22911
USA
Contact: Glenn Gerstenfeld
Title: VP, QA/RA and Compliance Officer
Phone: (434) 975-8344
Fax: (434) 975-4144

2. Date Prepared

November 4, 2022

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: Orthopedic

4. Predicate Device(s)

The predicate device for this submission is MicroAire's SmartRelease® Endoscopic Soft Tissue Release System (K181819). This predicate has not been the subject of a design-related recall. No reference devices were used in this submission.

5. Intended Use / Indication for Use Statement

Intended Use: The MicroAire® SmartRelease® Endoscopic Soft Tissue Release System is intended for use in minimally invasive ligament or fascia release.

Indications for Use: The MicroAire® SmartRelease® Endoscopic Soft Tissue Release System is indicated for:

- Carpal tunnel release in the wrist
- Cubital tunnel release in the elbow
- Trigger finger release in the hand

6. Device Description

MicroAire's SmartRelease Endoscopic Soft Tissue Release System is comprised of the following components: the SmartRelease Endoscope, the SmartRelease Handpiece, and the SmartRelease Standard and Onyx Blade Assemblies. The system includes a set of accessory 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.

Carpal Tunnel:

The MicroAire SmartRelease Endoscopic Soft Tissue Release System is comprised of an endoscope and a handpiece that holds a Disposable Blade assembly. The carpal tunnel device attaches to any standard video camera and light source used in endoscopic/arthroscopy procedures. The surgeon introduces the Disposable Blade assembly into the carpal tunnel through an incision in the proximal wrist flexion crease. Viewing the deep side of the transverse carpal ligament (flexor retinaculum) through a window at the tip of the instrument, the surgeon elevates the blade to cut the ligament as the instrument is withdrawn.

Cubital Tunnel:

The MicroAire SmartRelease Endoscopic Soft Tissue Release System is comprised of an endoscope and a handpiece that holds a Disposable Blade assembly. The cubital tunnel device attaches to any standard video camera and light source used in endoscopic procedures. The surgeon introduces the disposable blade assembly into the cubital tunnel through a 3-cm longitudinal incision between the medial epicondyle and olecranon. Viewing the roof of the cubital tunnel fascia through a window at the tip of the instrument, the surgeon elevates the blade to cut the fascia as the instrument is withdrawn.

Trigger Finger:

The MicroAire SmartRelease Endoscopic Soft Tissue Release System is comprised of an endoscope and a handpiece that holds a Disposable Blade assembly. The trigger finger device attaches to any standard video camera and light source used in endoscopic procedures. The surgeon introduces the

disposable blade assembly into the finger through a 1-cm incision in the flexion crease of the affected finger. Viewing the roof of the A1 Pulley through a window at the tip of the instruments, the surgeon elevates the blade to cut the pulley as the instrument is withdrawn.

7. Substantial Equivalence Discussion

Technological Characteristics

This submission is to add an Indication for Use to the SmartRelease Endoscopic Soft Tissue Release System and does not include any design changes to the product family. There have been no design changes between the originally cleared SmartRelease Endoscopic Soft Tissue Release System and the proposed product family. Thus, the two SmartRelease devices have the same technological characteristics as there have been no changes to the design, material, chemical composition, energy source, manufacturing, packaging, or sterilization of the device, as summarized in the table below.

Technological Characteristic	**SUBJECT** SmartRelease Endoscopic Soft Tissue Release System	**PREDICATE** **510(K) K181819** SmartRelease Endoscopic Soft Tissue Release System	**Comparison**
Design			
Mechanism of Action	The blade assembly locks onto the front of the handpiece. The endoscope is inserted through the handpiece into the blade assembly. A light source and camera are attached to the endoscope. When the blade assembly is inserted into the surgical site, the endoscope provides a view of the distal end of the blade assembly and tissue to be resected. When the user pulls the trigger on the handpiece, it advances the shuttle into the proximal end of the blade assembly, pushing the actuator forward. This forward movement of the actuator raises the cutting blade along a track in the blade case. With the cutting blade fully raised, the user can slowly pull the assembly back out of the surgical site, allowing the cutting blade to	The blade assembly locks onto the front of the handpiece. The endoscope is inserted through the handpiece into the blade assembly. A light source and camera are attached to the endoscope. When the blade assembly is inserted into the surgical site, the endoscope provides a view of the distal end of the blade assembly and tissue to be resected. When the user pulls the trigger on the handpiece, it advances the shuttle into the proximal end of the blade assembly, pushing the actuator forward. This forward movement of the actuator raises the cutting blade along a track in the blade case. With the cutting blade fully raised, the user can slowly pull the assembly back out of the surgical site, allowing the cutting blade to	Identical to predicate device

Technological Characteristic	SUBJECT SmartRelease Endoscopic Soft Tissue Release System	PREDICATE 510(K) K181819 SmartRelease Endoscopic Soft Tissue Release System	Comparison
	resect the tissue of interest. When the trigger is released, the force of the shuttle on the actuator is removed, and a spring in the blade assembly returns the actuator and cutting blade to their original, retracted position.	resect the tissue of interest. When the trigger is released, the force of the shuttle on the actuator is removed, and a spring in the blade assembly returns the actuator and cutting blade to their original, retracted position.	
Materials	• Handpiece – aluminum, stainless steel, Radel • Blade Assemblies – polyetherimide, polyacrylamide, stainless steel • Endoscope – stainless steel, titanium, PEEK, Sapphire glass, CASTIN lead-free solder • Sterilization Tray – stainless steel, silicone • Accessory Instruments – stainless steel	• Handpiece – aluminum, stainless steel, Radel • Blade Assemblies – polyetherimide, polyacrylamide, stainless steel • Endoscope – stainless steel, titanium, PEEK, Sapphire glass, CASTIN lead-free solder • Sterilization Tray – stainless steel, silicone • Accessory Instruments – stainless steel	Identical to predicate device
Single-Use / Reusable	• Blade Assemblies are single use, disposable devices • Handpiece, endoscope, sterilization tray, and accessory instruments are reusable devices	• Blade Assemblies are single use, disposable devices • Handpiece, endoscope, sterilization tray, and accessory instruments are reusable devices	Identical to predicate device
Shelf Life	Blade Assemblies have 4 year shelf life	Blade Assemblies have 4 year shelf life	Identical to predicate device
Energy Output	None	None	Identical to predicate device
Battery Operated	No	No	Identical to predicate device
AC Powered	No	No	Identical to predicate device

Technological Characteristic	SUBJECT SmartRelease Endoscopic Soft Tissue Release System	PREDICATE 510(K) K181819 SmartRelease Endoscopic Soft Tissue Release System	Comparison
Complies with ISO 10993-1	Yes, complies with ISO 10993-1:2018	Yes, complies with ISO 10993-1:2018	Identical to predicate device
Electrical Safety Testing	N/A	N/A	Identical to predicate device
Manufacturing			
Handpiece	Components machined both internally and by external suppliers. Anodized by external supplier. Assembled, labeled, and packaged internally.	Components machined both internally and by external suppliers. Anodized by external supplier. Assembled, labeled, and packaged internally.	Identical to predicate device
Endoscope	Manufactured, labeled, and packaged complete by external supplier.	Manufactured, labeled, and packaged complete by external supplier.	Identical to predicate device
Blade Assemblies	Components molded/ manufactured by external suppliers. Assembled, packaged, and labeled internally. Sterilized by external supplier.	Components molded/ manufactured by external suppliers. Assembled, packaged, and labeled internally. Sterilized by external supplier.	Identical to predicate device
Sterilization Tray	Manufactured, labeled, and packaged complete by external supplier.	Manufactured, labeled, and packaged complete by external supplier.	Identical to predicate device
Accessory Instruments	Manufactured and labeled complete by external supplier. Packaged internally.	Manufactured and labeled complete by external supplier. Packaged internally.	Identical to predicate device

Technological Characteristic	SUBJECT SmartRelease Endoscopic Soft Tissue Release System	PREDICATE 510(K) K181819 SmartRelease Endoscopic Soft Tissue Release System	Comparison
Packaging			
Reusable Devices	• Handpiece – placed in a Korrvu insert (plastic film and corrugated board), then placed in corrugated shipper box. • Endoscope – placed in a custom-fit foam insert, then placed in corrugated shipper box. • Sterilization Tray – shrink-wrapped with plastic film, then placed in corrugated shipper box. • Accessory Instruments – placed in poly bags, heat-sealed on both ends.	• Handpiece – placed in a Korrvu insert (plastic film and corrugated board), then placed in corrugated shipper box. • Endoscope – placed in a custom-fit foam insert, then placed in corrugated shipper box. • Sterilization Tray – shrink-wrapped with plastic film, then placed in corrugated shipper box. • Accessory Instruments – placed in poly bags, heat-sealed on both ends.	Identical to predicate device
Sterile Devices (blade assemblies)	Device placed in PETG Tray with Tyvek lid, heat sealed on all four sides. Tray placed in SBS box (single- or 6-pack configuration).	Device placed in PETG Tray with Tyvek lid, heat sealed on all four sides. Tray placed in SBS box (single- or 6-pack configuration).	Identical to predicate device
Sterilization			
Sterilization	• Blade Assemblies are provided sterile via gamma radiation, 25-40kGy • Handpiece, endoscope, and all accessories are provided non-sterile, to be cleaned and sterilized via steam autoclave by user prior to each use	• Blade Assemblies are provided sterile via gamma radiation, 25-40kGy • Handpiece, endoscope, and all accessories are provided non-sterile, to be cleaned and sterilized via steam autoclave by user prior to each use	Identical to predicate device

Performance Data

As the subject device is identical in construction, geometry, functionality, and Intended Use to its cleared predicate, previous testing provided in the cleared K181819 demonstrates that the SmartRelease

Endoscopic Soft Tissue Release System is safe and effective for its Intended Use. Nothing has changed with the SmartRelease System to alter that conclusion.

Shelf life testing originally submitted in K181819 was based on product that had undergone accelerated aging conditioning. Since that submission was cleared, performance testing has been completed on product that has undergone real time aging to support the labeling shelf life. All products under consideration passed this testing.

A new User Validation was performed with appropriate users for the subject device's new Indication for Use to evaluate the user interfaces and to confirm that the intended user groups can appropriately use the device and demonstrate that the device is safe and effective for the new Indication for Use. Twenty users participated in cadaver labs with the subject device, walking through the procedure for trigger finger release on both fingers and thumbs on multiple hands each, for a total evaluation of 80 fingers and 40 thumbs. The results confirm that the SmartRelease Endoscopic Soft Tissue Release System 1) presents no usability risks, 2) can be safely and effectively used as intended, and 3) meets the User Needs.

Intended Use

The Intended Use is identical between the subject device and predicate. The addition of the "Trigger finger release in the hand" Indication for Use does not change the Intended Use nor raise any concerns regarding safety or effectiveness, as discussed above.

8. Statement of Substantial Equivalence

The subject device, SmartRelease Endoscopic Soft Tissue Release System, is the identical product as its predicate, cleared under K181819. It has the same technological characteristics, same performance testing and results, and the same Intended Use as its predicate. The added Indication for Use does not raise new or different questions of safety or effectiveness, as demonstrated in the User Validation. Therefore, the subject SmartRelease Endoscopic Soft Tissue Release System is substantially equivalent to the predicate device.

9. Referenced Standards

The SmartRelease Endoscopic Soft Tissue Release System also complies in whole or in part to the following consensus standards.

- ISO 14971:2019, *Medical devices – Application of risk management to medical devices*
- ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- ISO 15223-1:2021, Medical devices – Symbol to be used with information to be supplied by the manufacturer – Part 1: General requirements
- ISO 20417:2021, Medical devices – Information to be supplied by the manufacturer

- IEC 62366-1:2020, Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging systems
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming sealing and assembly processes
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ANSI AAMI ST77:2013/(R)2018, Containment devices for reusable medical device sterilization
- ANSI AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

10. Conclusion

SmartRelease Endoscopic Soft Tissue Release System is substantially equivalent to the predicate device in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties. The SmartRelease Endoscopic Soft Tissue Release System is designed to comply with applicable federal safety and performance standards. The User Validation data support the new indication claim. There are no new safety and effectiveness issues.