November 6, 2018

MicroAire Surgical Instruments LLC
% Ms. Vikki O'Connor
Regulatory Affairs Consultant
Ambriel Associates, Inc.
411 Walnut St. Unit 9236
Green Cove Springs, Florida 32043

Re: K181819
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: October 4, 2018
Received: October 5, 2018

Dear Ms. O'Connor:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen

Digitally signed by Long H. Chen
Date: 2018.11.06 08:16:55 -05'00''

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

Device Name
MicroAire SMARTRELEASE® Endoscopic Soft Tissue Release System

Indications for Use (Describe)
The MicroAire 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

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: MicroAire SMARTRELEASE®
Endoscopic Soft Tissue Release System

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular, 21 CFR Part 807.92, the following summary of information is provided:

| Submitter: | MicroAire® Surgical Instruments Inc.  
3590 Grand Forks Blvd.  
Charlottesville, VA 22911 USA |
|---|---|
| Contact Person | Vikki M. O’Connor  
Regulatory Consultant  
Phone: 207-214-8535  
Email: vikki0730@yahoo.com |
| Correspondance | Mr. Glenn Gerstenfeld  
Vice President, QA/RA and Compliance Officer  
Phone: 434-975-8344  
FAX: 434-975-4144  
Email: glenn.gerstenfeld@microaire.com |
| Date Prepared | November 5, 2018 |
| Trade Name | MicroAire SMARTRELEASE® Endoscopic Soft Tissue Release System |
| Proposed Class | Class II |
| Classification Name and Number | Diagnostic Devices - Arthroscope, 21 CFR 888.1100, Class II  
Sterilization Container, 21 CFR 880.6580, Class II  
Manual Surgical Instrument, 21 CFR 878.4800, Class I |
| Product Code | HRX, KCT, EMF |
| Predicate Devices | Deployment Handle and Blade Assembly Primary  
Predicate – A.M. Surgical Mountable Endoscopic Blade - K080133 (Class I), A.M. Surgical STRATOS® Endoscopic |
<table>
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<th><strong>Release System</strong> – Carpal and Cubital Tunnel Release (Class I, no 510k). Reference: 3M Carpal Tunnel System - K881703 (Class II) Carpal Tunnel Release. <strong>Arthroscope Primary Predicate</strong> - Henke Sass Wolfe Arthroscope: K080560 (Class II); <strong>Sterilization Tray Primary Predicate</strong> - Paragon Medical Inc. Surgical Instrument Delivery System: K032119 (Class II);</th>
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<td><strong>Device Description</strong></td>
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| **Intended Use** | The MicroAire® 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 |
| **Subject Device Summary of the Technological Characteristics** | The SMARTRELEASE® Endoscope is a standard endoscope used in endoscopic / arthroscopic surgery. It connects to any standard C-mount video camera system for visualization and has a light post and two Light Post |
| Comparison to Predicate(s) | Adapters that attach to six of the most common light sources. There is no electrical source and the endoscope is re-usable after cleaning and heat sterilization.

The SMARTRELEASE® Handpiece has a pistol grip and trigger to facilitate raising and retracting the surgical blade. The SMARTRELEASE® Blade Assembly is designed to cut the carpal tunnel ligament or fascia release in the cubital tunnel with one retracting cut.

The SMARTRELEASE® Sterilization Tray is large enough, and segmented, to hold and heat sterilize all devices and instruments required to perform a carpal or cubital tunnel surgery. The sterilization tray meets the requirements set forth in ANSI AAMI ST 77:2003.

The SMARTRELEASE® Endoscope is made by contract manufacturer Henke Sass Wolf and is identical to the Henke Sass Wolf Arthroscope (K080560). This is the same arthroscope used in the 3M Carpal Tunnel System.

MicroAire’s SMARTRELEASE® Handpiece and Blade Assembly is similar in technology, materials and design to the predicates. The subject and predicate devices all provide technology to access the wrist or elbow to release the ligament or fascia during carpal or cubital tunnel surgery. The Handpieces are made of similar materials, hold the Blade Assembly and can deploy the blade to make a cut and retract the blade for removal of the device from the surgical area(s). The blades are made of 300/400 series stainless steel and are sharp enough to cut fascia /
ligament and are biocompatible.

The subject and predicate tray are made from 300 Series Stainless Steel and hold all devices that require re-sterilization. The subject sterilization tray includes a silicon mat.

| Summary of Supporting Data | The following functional testing was performed to verify the following basic functions of the Handpiece and Blade Assembly: Blade Assembly Actuation, Horizontal and Vertical Deflection, Blade Sharpness and Blade Piercing. The system was also evaluated by multiple surgeons per the instructions for use during a cadaver study. All test results demonstrated the MicroAire SMARTRELEASE Soft Tissue Release System can perform it's intended use safely and effectively.

In addition, the SMARTRELEASE® Endoscopic Soft Tissue Release System passed package and distribution testing and applicable biocompatibility testing. |
Summary / Conclusion
MicroAire’s SMARTRELEASE® Endoscopic Release System is comprised of the SMARTRELEASE® Handpiece and SMARTRELEASE® Blade Assembly(s) which are FDA Class I Manual Surgical Instruments. The addition of the dedicated SMARTRELEASE® Endoscope to the system and a Sterilization Tray for re-sterilizing the Endoscope, Handpiece and Class I instruments make the overall system a Class II device.

Basic device functional tests and a cadaveric study by multiple surgeons were performed to evaluate the system for the intended use. All test results demonstrated the MicroAire SMARTRELEASE Soft Tissue Release System can perform the intended use safely and effectively.