February 6, 2024

E Surgical, LLC
℅ Craig Coombs
President
Coombs Medical Device Consulting, Inc.
427 14th Ave
San Francisco, California 94118

Re: K233115
Trade/Device Name: Hawkeye Control Unit with Eyas Endoscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: January 8, 2024
Received: January 9, 2024

Dear Craig Coombs:

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.

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.02.06 08:00:02 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233115

Device Name
Hawkeye Control Unit with Eyas Endoscope

Indications for Use *(Describe)*
The Hawkeye Control Unit with Eyas Endoscope is intended for use in diagnostic and operative arthroscopic and endoscopic procedures to provide visualization and image capture of an interior body cavity through a surgical incision.

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

A. Device Information:

Category	**Comments**
Sponsor:	E SURGICAL, LLC 150 Isidor Ct, Ste 203, Sparks, NV 89441
Correspondent Contact Information:	Mr. Craig Coombs President Coombs Medical Device Consulting, Inc. 427 14th Ave, San Francisco, CA, 94118 Tel: 650-380-2474 Email: craigJcoombs@gmail.com
Device Common Name:	Arthroscope
Device Classification Number:	21 CFR 888.1100
Device Classification & Product Code:	Class II, HRX
Device Proprietary Name:	Hawkeye Control Unit with Eyas Endoscope

Predicate Device Information:

Predicate Device :	Trice medical mi-eye2, mi-eye 2 monitor
Predicate Device Manufacturer:	Trice Medical
Predicate Device Common Name:	Arthroscope
Predicate Device Premarket Notification #	K162475
Predicate Device Classification:	21 CFR 888.1100 Arthroscope
Predicate Device Classification & Product Code:	Class II, HRX

B. Date Summary Prepared

30 January 2024

C. Description of Device

The E Surgical Hawkeye Control Unit with Eyas Endoscope is an arthroscope system, consisting of the Hawkeye Control Unit (Medical Tablet plus Console Box), and the

Eyas Endoscope. The Medical Tablet is a touch panel computer for the system function control, endoscope image displays and operation data storage. The Eyas Endoscope is a hand-held, single-use device for accessing the interior of a joint to capture the real-time image of the target site through a small incision. The Console Box is an interface between the Medical Tablet and Eyas Endoscope.
There are 10 models of Eyas Endoscope in this system; including 2 different directions of view (0^o and 30^o) in combination with 5 different working lengths. All these models must be used in conjunction with Hawkeye Control Unit to perform as intended.
The E Surgical Hawkeye Control Unit with Eyas Endoscope is also capable recording and storing the images in the system for later review.

D. Indications for Use

The Hawkeye Control Unit with Eyas Endoscope is intended for use in diagnostic and operative arthroscopic and endoscopic procedures to provide visualization and image capture of an interior body cavity through a surgical incision.

E. Comparison to Predicate Device

The comparison between E Surgical Hawkeye Control Unit with Eyas Endoscope and the predicate devices are:

Feature	**Application Device:** *E Surgical Hawkeye Control Unit with Eyas Endoscope*	**Predicate:** *Trice medical mi-eye2, mi-eye 2 monitor (K162475)*	**Pertinence of Feature to Consideration of Substantial Equivalence**
Indications for Use	The Hawkeye Control Unit with Eyas Endoscope is intended for use in diagnostic and operative arthroscopic and endoscopic procedures to provide visualization and image capture of an interior body cavity through a surgical incision.	The mi-eye2 is indicated for use in diagnostic and operative arthroscopic and endoscopic procedure to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.	Identical
Product Code	HRX	HRX	Identical

Feature	**Application Device:** *E Surgical Hawkeye Control Unit with Eyas Endoscope*	**Predicate:** *Trice medical mi-eye2, mi-eye 2 monitor (K162475)*	**Pertinence of Feature to Consideration of Substantial Equivalence**
Operating Principle	Transmission of light to illuminate and image an arthroscopic joint, then relaying the image out of the surgical site for processing and display.	Transmission of light to illuminate and image an arthroscopic joint, then relaying the image out of the surgical site for processing and display.	Identical
Input Power	100 - 240 V	100 - 240 V	Identical
Technology			
Light source	LED(SMD Type)	LED(SMD Type)	Identical
Image File Format	PNG	PNG	Identical
Video file Format	MPG	AVI(or MP4)	Functionally identical. These two video formats are applied for different media players.
Output port	USB,HDMI, Audio jack	USB	Functionally identical. Per cybersecurity report, image and audio output through HDMI and audio jack do not raise safety or effectiveness concerns.
Physical Specification (Tablet)			
Principle Component	Tablet, Console Box, Endoscope	Tablet, Endoscope	Similar. The application device has a console box that powers the tablet and endoscope, and severs as a stand to position the tablet. This design difference does not affect the safety and performance of the product.

Feature	**Application Device:** *E Surgical Hawkeye Control Unit with Eyas Endoscope*	**Predicate:** *Trice medical mi-eye2, mi-eye 2 monitor (K162475)*	**Pertinence of Feature to Consideration of Substantial Equivalence**
Dimensions	Tablet: 28 cm x 18 cm x 1.83 cm Console Box: 16.9 cm x 19.6 cm x 12.2 cm	Tablet: 33.5 cm x 21.6 cm x 3.8 cm	Similar. The difference in design mechanisms does not raise any safety or effectiveness concerns.
Weight	Tablet:2.2 lb (1 kg) Console: 2.2 lb (1 kg)	3.72 lb (< 1.69 kg)	
Display	10.1" LCD	12.3" LCD	
Working Condition	Temperature range: 10℃ to 30℃ Humidity range: 30%≤RH≤ 75% Atmospheric Pressure: 700 hPa to 1013 hPa	Temperature range: 10℃ to 32℃ Humidity range: 30%≤RH≤ 95% Atmospheric Pressure: 700 hPa to 1060 hPa	Minor Differences. The internal circuit design and components chosen are different, but have specifications for similar working, transport and storage conditions. The temperature, RH and atmospheric pressure specifications are similar and are typical working conditions. These specifications are considered to be substantially equivalent.
Transport and Storage Condition	**Ambient temperature:** -20℃ to +60℃ **Humidity range:** 25% to 85%, non-condensing. **Atmospheric pressure:** 500 hPa to 1013 hPa	**Ambient temperature:** -20℃ to +60℃ **Humidity range:** 10% to 100%, non-condensing. **Atmospheric pressure:** 500hPa to 1060 hPa	
Materials			
Probe & Patient contacting features	SUS 304, ABS, PC (polycarbonate), Copper Clad Laminate, Polyimide, $CaZro_3$, Expoy Resin, Acrylate Urethane, Silicone	SUS 304	Biologically identical
Special Functions			

Feature	**Application Device:** *E Surgical Hawkeye Control Unit with Eyas Endoscope*	**Predicate:** *Trice medical mi-eye2, mi-eye 2 monitor (K162475)*	**Pertinence of Feature to Consideration of Substantial Equivalence**
Audio indicator	Yes, operating & warning tone	No	The application device has operating and warning tone to remind use, while the predicate has visual signal only.
Flushing feature	Yes. The Eyas endoscope requires connecting to a cannula to achieve the flushing feature.	Yes. The integrated rigid shaft that extends from the mi-eye2 endoscope handle can be utilized to achieve flushing feature.	Functionally identical.
Others			
Endoscope Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Operation Environment	Operating rooms, treatment rooms, and clinics.	Operating rooms, treatment rooms, and clinics.	Identical
Standard Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 ISO 10993-1 ISO 11135	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 ISO 10993-1 ISO 11135-1	Almost identical, application device is in conformance with latest version of the listed standards

F. Bench Testing Summary

The Bench Testing for the Hawkeye Control Unit with Eyas Endoscope is summarized below.

Hawkeye Control Unit	
Device	
Console Box	Visual Inspection/ Power Supply/ Plug Insertion & Extraction Force
Medical Tablet	Visual Inspection/ Luminance Adjustment/ Capturing and Recording / Battery Capacity Check/ Tablet Charging/ Software Version/ Firmware Version/ HDMI Signal Output/ Image Function/ USB Storage/Tone (button operation)/ Tone (warning alert)
Package	

Hawkeye Control Unit	
Package Inspection	Package and Device Integrity, Label Visibility

Eyas Endoscope	
Device	
Electrical	EEPROM Function/ Continuity Resistance
Optical	Luminance Intensity/ Sensitivity/ White Balance/ SFR/ Uniformity/ Color Response/ Dust Spot/ Dark/ Noise/ Stray Light/ Color Performance/Direction of View/ Field of View
Mechanical	Activation Force/ Plug Insertion & Extraction Force/ Dynamic Strain Relief/ Static Strain Relief/ Weld Integrity / Camera Tube Wobble/ Activation Over Time/ Leakage/Fluid Ingress Test
Package	
Package Integrity	Visual Inspection/Peel Open / Seal Width/ Seal Strength / Dye Leak

G. Summary of Supporting Data

The application E Surgical Hawkeye Control Unit with Eyas Endoscope were tested and found to be in compliance with the pertinent portions of the following standards,

Standards Body & #	Standard Name	Standard Version
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005 + AM1:2012
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	2017 + AM1:2020
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	2009
IEC 62304	Medical device software — Software life cycle processes	2006+AM1:2015
ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.	2018
ISO 11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	2014 + AM1: 2018

Standards Body & #	Standard Name	Standard Version
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems;	2019
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	2019

G. Conclusion

After comparing the indications for use, technology and design of the E Surgical Hawkeye Control Unit with Eyas Endoscope, along with all electrical safety (including IEC 60601-1; IEC 60601-1-2; IEC 60601-2-18) and relevant performance, in accordance with FDA-recognized consensus standards for electrical safety, E Surgical concludes that the Hawkeye Control Unit with Eyas Endoscope is substantially equivalent to the predicate Trice medical mi-eye2, mi-eye 2 monitor (K162475).