September 15, 2021

Trice Medical, Inc.
David Vancelette
Vice President of Quality Assurance & Regulatory Affairs
40 General Warren Blvd, Suite 100
Malvern, Pennsylvania 19355

Re: K212556
Trade/Device Name: mi-eye 3 needlescope™ with cannula, mi-tablet 3™
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 12, 2021
Received: August 13, 2021

Dear David Vancelette:

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,

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)*
K212556

Device Name
mi-eye 3 needlescope™ with cannula, mi-tablet 3™

Indications for Use *(Describe)*
The mi-eye 3 needlescope™ with cannula, mi-eye tablet 3™ is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

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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1. 510(k) Summary

Date	September 14, 2021
Applicant	Trice Medical, Inc. 40 General Warren Blvd Suite 100 Malvern, PA 19355 Tel: (610) 989-8080 Fax: (610) 706-5063
Official Correspondent	David Vancelette Trice Medical, Inc. 40 General Warren Blvd Suite 100 Malvern, PA 19355 dvancelette@tenexhealth.com Tel: (949) 238-8220 Fax: (949) 580-1270
Trade Name	mi-eye 3 needlescope™ with cannula, mi-tablet 3™
Common Name	Arthroscope
Device Classification	Class II, 21 CFR §888.1100
Product Code	HRX: Arthroscope
Predicate device	mi-eye 2, mi-eye 2 monitor (K162475), now rebranded as mi-eye 3, mi-tablet 3
Submission Type	Special 510(k). The subject device is a modification to the previously cleared mi-eye 2, mi-eye 2 monitor (K162475).

Substantially Equivalent To:

The mi-eye 3 needlescope™ with cannula, mi-tablet 3™ is substantially equivalent to the previously cleared mi-eye 2, mi-eye 2 monitor (K162475).

Description of the Device Subject to Premarket Notification:

The mi-eye 3 needlescope™ with cannula, mi-tablet 3™ is a portable visualization device that uses a probe with integrated camera and separate LCD monitor attached via a cable. The sterile, single-use needlescope probe includes the camera and image capture features with

LED light source. The mi-eye 3 probe connects to, and is powered by, the reusable mi-tablet 3. The mi-tablet 3 includes an internal battery and power supply, along with a cable for external charging. The mi-tablet 3 LCD Monitor displays a real-time image from the probe. The Monitor is also capable of connecting to separate ultrasound transducer, linear and convex, imaging probes and displaying their visual output. The mi-eye 3 needlescope™ with cannula has a rigid shaft that extends from the handle. The distal tip of the probe contains the camera, illumination, and imaging optics. Irrigation may be provided through the distal end of the probe from user supplied solution attached to the handle.

The mi-eye 3 needlescope™ with cannula is available in 75 and 95mm lengths with 0 and 25 degree viewing angles, relative to the axis of the probe. The probe is packaged with a scalpel, cannula, obturator and switching stick for use in creating and maintaining the channel for the probe. The monitor has a 12" (diagonal) screen. The probe weight is under 300 grams.

INDICATIONS FOR USE:

The mi-eye 3 needlescope™ with cannula, mi-tablet 3™ is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Property	Subject Device mi-eye 3 needlescope™ with cannula, mi-tablet 3™	Predicate Device mi-eye 2, mi-eye 2 monitor
510(k) Number	N/A	K162475
Indications for Use	The mi-eye 3 with cannula is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.	Same
Operating Principles	Transmission of light to illuminate and image an arthroscopic joint, then relaying the image out of the surgical site for processing and display.	Same

Property	Subject Device mi-eye 3 needlescope™ with cannula, mi-tablet 3™	Predicate Device mi-eye 2, mi-eye 2 monitor
Principle Components	• Imaging Probe with camera, rigid shaft, handle and output cable. • LCD Display Monitor • Irrigation channel for user supplied solution • Scalpel, Cannula, Obturator and Switching Stick (for establishing arthroscope channel)	Same Same Same N/A
Materials		
Probe & Patient contacting features	304 Stainless Steel	Same
Battery	Lithium Ion	Same
Technological Characteristics		
Probe Handle Size	35 - 55mm diameter	Same
Probe Needle Outer Diameter	2.3mm	Same
Probe Cannula Outer Diameter	2.9mm	None
Working Probe Lengths	75 and 95mm	50, 95, 120 and 160mm
Camera Angle	0 and 25 degrees	0 and 15 degrees
Camera + Display Resolution	400 x 400	Same
Image leveling	Image stabilized for probe's position (display does not rotate). Arrow indicating the top side of probe handle rotates in the image.	Top of probe always oriented at top of display (display rotates as probe rotates)
Tablet Operating System	MS Windows 10 Pro	Same
Display output	HDMI and SDI	Same
Media capture	USB, DB9 and TRS	Same
Irrigation with Angled View Probe	User attached solution is channeled through the annulus between the two tubes to the distal end of the probe	None
Packaging for Single Use Probe	Sealed Tyvek lid and thermal formed tray	Same
Sterilization Method	Ethylene Oxide	Same
Sterility Assurance Level	10^{-6}	Same

PERFORMANCE DATA:

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

Test	Method	Result
Biocompatibility	ISO 10993-1 ISO 10993-5	Pass
Electrical Safety & EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 IEC 60529	Pass
Packaging	ASTM D4169, ASTM F2096, ASTM F88/F88M, ISO 11607-1, ISO 11607-2	Pass
Performance – Bench Irrigation Flow Tube strength	 ISO 9626	Pass
Shelf Life	ASTM F1980, ASTM F88/F88M, ISO 11607-1, ISO 11607-2	Pass
Software V&V	IEC 62304	Pass
Specification & Dimensional Analysis	ISO 594-1, ISO 594-2, ISO 7864, ISO 80369-7, ISO 9626	Pass
Sterilization	ISO 11135, ISO 11737-1, ISO 10993-7	Pass
Usability Validation	IEC 60601-1-6, IEC 62366-1	Pass

CONCLUSION:

The mi-eye 3 needlescope™ with cannula, mi-tablet 3™ Arthroscope is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no new issues of safety and/or effectiveness introduced by the mi-eye 3 needlescope™ with cannula, mi-tablet 3™ Arthroscope when used as instructed.