DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 16, 2016

Trice Medical, Inc.
Ms. Tiffini Diage
Consulting Director, Regulatory Affairs
1000 Continental Dr. Suite 240
King Of Prussia, Pennsylvania 19406

Re: K162475
Trade/Device Name: mi-eye 2, mi-eye 2 Monitor
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 30, 2016
Received: September 7, 2016

Dear Ms. Diage:

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. 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 Part 803); good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Christopher J. Ronk -S

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162475

Device Name
mi-eye 2, mi-eye 2 monitor

Indications for Use *(Describe)*
The mi-eye 2 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter:	Trice Medical, Inc. 1000 Continental Drive, Suite 240 King of Prussia, PA 19406
Contact Person:	Tiffini Diage Consulting Director Regulatory Affairs Phone: 707.799.6732 E-mail: tdiage@raechelon.com
Trade Name:	mi-eye 2, mi-eye 2 Monitor
Common Name:	Arthroscope
Classification:	Class II
Product Code:	HRX, 888.1100
510(k) Number	K162475
Predicate Device(s):	The subject device is equivalent to the following devices: • K141119 – mi-eye Camera Enabled Probe
Device Description:	The Camera Enabled Probe is a battery operated, portable, visualization device that uses a probe with integrated camera and separate LCD monitor attached via cable. The sterile, single-use probe includes the camera and image capture features with LED light source. The LCD Monitor displays real-time video from the probe and is attached via cable to provide power to the probe. The probe scope extends from the handle as a rigid shaft with retractable needle and flushing port for cleaning the field of view. The distal tip of the probe contains the camera, illumination, and imaging optics. The mi-eye 2 devices are identical in design and function and available in three lengths: 50mm, 95mm, and 160mm. The monitor has a 10.8” (diagonal) screen. The entire unit weight is less than 300 grams.
Indication for Use:	The mi-eye 2 device 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.

Functional and Safety Testing:	To verify that device design meets its functional and performance requirements, representative samples of the device underwent biocompatibility, software, electrical, and mechanical testing in accordance with the following industry standards. ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ANSI / AAMI / EN-60601-1-2 Medical Electrical Equipment -- Part 1-2: General Requirements for Basic Safety and Essential Performance ISO-11135-1 › Sterilization of Health Care Products. Ethylene Oxide. Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices ISO-9626 › Stainless Steel Needle Tubing for the Manufacture of Medical Devices ISO-7864 › Sterile Hypodermic Needles for Single Use
Conclusion:	The changes made to the previously cleared mi-eye Camera Enabled Probe (now called mi-eye 2) device do not affect the established safety and efficacy of the device. Mi-eye 2 is equivalent to the predicate device. This conclusion is based upon the devices' identical indications for use, principles of operation, technology, and performance specifications. The changes made were tested using the same acceptance criteria as the predicate device and provide objective evidence that there are no new risks and the device is substantially equivalent.