June 8, 2022

MicroSurgical Technologies Inc
Ms. Angela Mallery
Principle Product Development Strategist, Regulatory
8415 154th Ave NE
Redmond, Washington 98052

Re: K213173
Trade/Device Name: TrabEx Pro
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MRH
Dated: May 3, 2022
Received: May 3, 2022

Dear Ms. Angela Mallery:

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,

Anjana Jain, PhD
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K213173

Device Name
TrabEx Pro

Indications for Use *(Describe)*
The TrabEx Pro Handpiece is a manual ophthalmic surgical instrument with irrigation and aspiration functions.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

<table>
<tr><td>Submitted by:</td><td>MicroSurgical Technology, Inc.
8415 154th Ave NE Redmond, WA 98052
(425)861-4002
www.microsurgical.com</td></tr>
<tr><td>Date Prepared</td><td>June 7, 2022</td></tr>
<tr><td>Contact</td><td>Dave Scott
COO
(425)861-4002
info@microsurgical.com</td></tr>
<tr><td>Trade/Proprietary Name</td><td>TrabEx Pro</td></tr>
<tr><td>Regulatory Name and Classification</td><td>Infusion Pump;
21 CFR 880.5725 (Product code: MRH)</td></tr>
<tr><td>Predicate</td><td>K993039 Bausch & Lomb Storz Millennium Viscous Fluid Injector System</td></tr>
<tr><td>Reference Devices</td><td>K040584 Trabectome</td></tr>
<tr><td>Device Description</td><td>The MicroSurgical Technology TrabEx Pro is a single use, sterile, manual ophthalmic knife. The device can be connected to an ophthalmic Irrigation/Aspiration (I/A) system to provide irrigation and aspiration while the procedure is being performed.
TrabEx PRO has an incision sealing sleeve.</td></tr>
<tr><td>Indications for Use</td><td>The TrabEx Pro Handpiece is a manual ophthalmic surgical instrument with irrigation and aspiration functions.</td></tr>
<tr><td>Comparative Technology Characteristics</td><td>The subject and predicate device both include an irrigation and aspiration feature.
This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.</td></tr>
<tr><td>Technological Characteristics</td><td>Irrigation/aspiration performance of the TrabEx Pro was compared to the Trabectome (K040584) to demonstrate substantial equivalence of the TrabEx Pro to the Trabectome.
The TrabEx Pro and the Trabectome were tested using the same test methods for establishing irrigation and aspiration rates; the rates are identical.
<table>
<tr><th colspan="3">Irrigation and Aspiration Rates</th></tr>
<tr><th></th><th>Subject device
TrabEx Pro</th><th>Trabectome
K040584</th></tr>
<tr><td>Intended Use</td><td>Ophthalmic surgical instrument</td><td>Ophthalmic surgical instrument</td></tr>
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</td></tr>
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	Ability for Irrigation and Aspiration	Irrigation Rate Min 3 ml/min at 40 cm bottle height (0.59 psi)	Irrigation Rate Min 3 ml/min at 40 cm bottle height (0.59 psi)
		Aspiration Rate 4 ml/min at no more than 250 mmHg (4.8psi)	Aspiration Rate 4 ml/min at no more than 250 mmHg (4.8psi)

Non-Clinical tests performed	Bench Testing	The Trabectome was identified as a reference device for demonstration of acceptable performance for the irrigation/aspiration function-under review
	Biocompatibility	TrabEx Pro is an external communicating device with limited (<24 hours) contact with tissue. The device components with direct and indirect tissue contact were assessed for biocompatibility per FDA Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" and included the following tests: • Cytotoxicity (test extract method) • Guinea pig maximization • Ocular Irritation • Acute systemic toxicity • Material mediated pyrogenicity The primary packaging does not contact the device components with direct tissue contact and was evaluated using chemical characterization assessment."
	Sterility	The TrabEx Pro was adopted into an existing radiation sterilization process. The radiation sterilization dose range provided a Sterility Assurance Level (SAL) of 10^{-6} in accordance with FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" issued on January 21, 2016. Limulus Amebocyte Lysate (LAL) testing was performed to support the direct and indirect contacting components of the TrabEx Pro are non-pyrogenic.
	Shelf Life	The labeled 2-year shelf life was supported with device performance testing and package integrity testing as per ISO 11607-1 and -2:2019, "Requirements for materials, sterile barrier systems and packaging systems." Samples were aged in compliance with ASTM F1980-16, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices."
Conclusion	Conclusion(s) drawn from the nonclinical tests demonstrate the device is substantially equivalent to the identified legally marketed device.	