August 19, 2024

SamanTree Medical SA
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K241275
Trade/Device Name: Histolog® Scanner (Hardware 2.4, Software 3.3)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: July 18, 2024
Received: July 18, 2024

Dear Cindy Domecus:

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,

Jessica Carr -S

Jessica Carr, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.

Submission Number *(if known)*

K241275

Device Name

Histolog® Scanner (Hardware 2.4, Software 3.3)

Indications for Use *(Describe)*

The Histolog® Scanner is a confocal laser system intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells, vessels and their organization or architecture.

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

This Summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

I. APPLICANT INFORMATION

Date prepared:	August 16, 2024
Submitter:	Olivier Delporte, CEO SamanTree Medical SA Avenue de Provence 12, 1007 Lausanne, Switzerland +32 475 95 8054 olivier.delporte@samantree.com
Submission Correspondent:	Cindy Domecus, R.A.C. Principal, Domecus Consulting Services LLC Regulatory Consultant to SamanTree Medical SA +1 650-773-3445 Cindy@DomecusConsulting.com

II. DEVICE INFORMATION

Device Trade Name:	Histolog® Scanner
Classification Name:	Confocal Optical Imaging
Product Code:	OWN
Classification:	Class II

III. PREDICATE DEVICE

The predicate device is the Cellvizio 100 Series Confocal laser Imaging systems and their Confocal Miniprobes, Mauna Kea Technologies, K183640.

IV. DEVICE DESCRIPTION

The Histolog® Scanner is a digital microscopy scanner for use on excised human tissue. Its operating principle is based on confocal fluorescence microscopy and uses non-ionizing, low-power optical radiation (Class 1 laser product as per IEC 60825-1:2014-05). The Histolog® Scanner acquires digital images with high, micrometer-range resolution and enables the visualization of tissue microstructures down to the cellular level.

The Histolog® Scanner is based on a massively parallel signal acquisition and processing technology providing fast digital imaging over large areas. Image reconstruction does not involve any image stitching or any other similar image blending algorithms. Each pixel in the image is assigned an intensity value based on the light intensity collected by the detector for this particular position in the scan pattern.

The Histolog® Scanner and its accessory devices are intended to be operated by trained healthcare professionals.

V. INDICATIONS FOR USE

The Histolog® Scanner is a confocal laser system intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells, vessels and their organization or architecture.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological Characteristic	Subject Device	Predicate Device	Comment
Measurement Technique	Laser-scanning optical microscopy [Confocal Laser Scanning Microscopy]	Laser-scanning optical microscopy [Confocal Laser Scanning Microscopy]	**SAME**
Optical Source	Laser	Laser	**SAME**
Center Wavelength	488 nm	488 nm	**SAME**
Optical Radiation Safety	Safe for Indicated Use, Class 1 Laser	Safe for Indicated Use, Class 2M Laser	**SIMILAR** This difference does not raise different questions of safety and effectiveness. Both are laser products evaluated as per IEC 60825-1. The subject device has lower accessible irradiation level than the predicate device.
Lateral Resolution	2 µm	1 µm or 3.5 µm depending on the model of Confocal Miniprobe	**SIMILAR** This difference does not raise different questions of safety and effectiveness. Both devices allow visualizing tissue microstructures at the micrometer scale.
Patient Applied Part	No Patient Applied Part	Handheld Fiber Optic Probe	**DIFFERENT** This difference does not raise different questions of safety

Technological Characteristic	Subject Device	Predicate Device	Comment
			and effectiveness, as discussed above.
Field of view	Square 250 µm x 250 µm (individual miniprobe) 4.8 cm x 3.6 cm (array of 192 x 144 miniprobes)	Circular 240 µm, 325 µm or 600 µm diameter depending on the Confocal Miniprobe model	**DIFFERENT** The individual image size of the Histolog is substantially the same as Cellvizio; 240 round versus 250 square. This difference does not raise different questions of safety and effectiveness, as discussed above.

VII. PERFORMANCE DATA

The performance tests summarized in the table below, demonstrate that the use of Histolog® Scanner is as safe and effective as the predicate device.

Test Performed	Acceptance Criteria	Test Results Subject device
Biocompatibility (Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity & Systemic toxicity)	ISO 10993-1 Edition 5 All applicable requirements met	Not applicable, as device does not have direct or indirect patient contact
Basic Safety	IEC 61010-1 Edition 3.1 + gaps towards IEC 60601-1 Edition 3.2 All applicable requirements met	PASS
EMC	IEC 60601-1-2 Edition 4.1 All applicable requirements met	PASS
Laser safety	IEC 60825-1 Edition 3.0 All applicable requirements met	PASS
Imaging Quality	Histolog® Scanner system imaging requirements verification protocols.	PASS

Test Performed	Acceptance Criteria	Test Results Subject device
	All requirements met	
Performance	Histolog® Scanner system performance requirements verification protocols. All requirements met	PASS
Cleaning	Cleaning Agent Compatibility Verification for Cleaning All requirements met	PASS

VIII. CONCLUSIONS

The Histolog® Scanner, has been shown to be substantially equivalent to the cleared predicate device and can be used as intended to image the internal microstructure of tissues in a variety of anatomical locations.

Based upon the intended use; product technical information; and performance, safety and effectiveness data provided in this submission, the subject device is substantially equivalent to the predicate device. The subject device can safely and effectively be used to visualize excised human tissue microstructure.