November 1, 2024

Mvitro Co., Ltd.
% Do-Hyun Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86gil 5,
Gangnam-gu
Seoul, 06210
Korea, South

Re: K241646
Trade/Device Name: Ortiv (ortiv-bl, Ortiv-wh)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 2, 2024
Received: October 2, 2024

Dear Do-Hyun Kim:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for Yan Fu -S Digitally signed by Yan Fu -S Date: 2024.11.01 13:48:27 -04'00'

Tanisha Hithe
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)*

K241646

Device Name

ORTIV (ORTIV-BL, ORTIV-WH)

Indications for Use *(Describe)*

The ORTIV is a portable, battery-operated laser lancing device indicated for obtaining capillary blood samples in both institutional and at-home settings.

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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510(k) Summary - K241646

1 General Information

Applicant/Submitter:	MVITRO Co., Ltd.
Address:	2F Hannam Bldg., 254 UN Village-gil Yongsan-gu, Seoul, 04420 Republic of Korea
Contact Person:	Do Hyun Kim, BT Solutions, Inc.
Address:	Unit 904, Eonju-ro 86gil 5, Gangnam-gu, Seoul 06210, Korea. Tel: +82-2-538-9140 Email: ceo@btsolutions.co.kr Email: smanager@btsolutions.co.kr
Preparation Date:	May 30, 2024

2 Device Name and Code

Device Trade Name:	ORTIV
Model Name:	ORTIV-BL, ORTIV-WH
Common Name:	Laser lancet
Classification Name:	Powered Laser Surgical Instrument
Product Code:	GEX
Regulation Number:	21 CFR 878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery

3 Technical Characteristics in Comparison to Predicate Devices

The ORTIV is substantially equivalent to the following legally marketed predicate device.

Table 1: Comparison of the proposed device to the predicate device K172818

	Proposed Device	K172818	Equivalence
Company	MVITRO Co., Ltd.	Lameditech Co., Ltd.	-
Product name	ORTIV	LMT-3000	-
Product code	GEX	GEX	YES
Regulation number	21 CFR 878.4810	21 CFR 878.4810	YES
Classification	Class II	Class II	YES
Intended Use	The ORTIV is a portable, battery-operated laser lancing device	The LMT-3000 is a portable, battery-operated laser lancing device	YES

	indicated for obtaining capillary blood samples in both institutional and at-home settings.	indicated for obtaining capillary blood samples in both institutional and at-home settings.	
Technological characteristics			
Wavelength	2940 nm	2940 nm	
Laser source	Er:YAG	Er:YAG	
Laser class	Class 3R (IEC 60825-1)	Class 4 (IEC 60825-1)	Different
Mechanism of Action	The laser lancet installed on the ORTIV is a pulsed Erbium YAG (ER: YAG) laser. It outputs a single pulse of laser light with a wavelength of 2940 nm, which ablates a small hole in the skin to a depth sufficient to access capillary blood.	The LMT-3000 Laser Skin Perforator is a pulsed erbium doped yttriumaluminum- garnet (Er:YAG) laser. It outputs a single pulse of laser light with a wavelength of 2940 nm, which ablates a small hole in the skin to a depth sufficient to access capillary blood.	YES
Technology Overview	The wavelength of this laser is 2940 nm, which matches water's absorption peak. Considering that water is the major constituent of organic tissue, it's possible to explain the strong absorption of tissue for this wavelength. On the other hand, due this strong absorption in water, this laser exhibits a little penetration depth.	The wavelength of this laser is 2940 nm, which matches water's absorption peak. Taking into account that water is the major constituent of organic tissue, it's possible to explain the strong absorption of tissue for this wavelength. On the other hand, due this strong absorption in water, this laser exhibits a little penetration depth.	YES
Battery Operated	Rechargeable battery (3.7 Vdc)	Rechargeable battery (3.7 Vdc)	YES
Laser pulse repetition rate	Single	Single	YES
Anatomical location	Fingers	Fingertips	YES
Operating humidity	10-90%	Relative humidity 5 to 90%, noncondensing	Similar
Operating temperature	10 ~ 40°C	Ambient temperature +5 to +40°C	Similar
Storage temperature	10 ~ 40°C	Ambient temperature -10 to +60°C	Similar
Storage humidity	10-90%	Relative humidity 5 to 90%, noncondensing	Similar
Sterile	No	No	YES
Material	Polycarbonate	Polycarbonate	YES
Single-Use	No	No	YES
Laser Power range	150 mJ (±20%)	Unknown	N/A
Applied part type	BF	BF	YES
Intended for	Prescription Use	Prescription Use	YES

4 Device Description

ORTIV laser lancet is a portable, battery-operated laser lancing device, and is indicated for obtaining capillary blood samples in both institutional and at-home settings. The laser is a pulsed Erbium YAG (ER: YAG). It outputs a single pulse of laser light with a wavelength of 2940 nm, which ablates a small hole in the skin to a depth sufficient to access capillary blood.

5 Indications / Intended Use

The ORTIV is a portable, battery-operated laser lancing device indicated for obtaining capillary blood samples in both institutional and at-home settings.
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6 Performance Data

Non-clinical tests for laser lancet:

The safety of laser product, electromagnetic compatibility and electrical safety, etc, were tested using following consensus standards:

- Basic safety and essential performance of the ORTIV is tested and evaluated according to the FDA-recognized consensus standard, IEC 60601-1:2020.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2:2014 +AMD1:2020.
- Safety of laser product is evaluated in accordance with IEC 60825-1: 2014.
- Risk management was recorded by referring to ISO 14971:2007.
- Usability was documented by referring to ISO 62366-1:2020.
- Biocompatibility testing per ISO 10993-1

7 Substantial Equivalence

The proposed device uses similar or identical technology as the predicate devices and has the same intended uses. Based upon the predicted overall performance characteristics for the ORTIV, MVITRO Co., Ltd., believes that there are no significant differences in usage of its underlying technological principles between the ORTIV and the predicate devices.

8 Conclusions

On the basis of the information provided in this Summary, MVITRO Co., Ltd., believes that the ORTIV is substantially equivalent to legally commercialized predicate devices for the purposes of these 510 (k) submissions.