June 23, 2025

OPXION Technology Inc.
% Ming-Yie Jan
Principal Consultant
RUSCERT Technology Co., LTD.
8F., No. 187, Lequn 2nd Rd., Zhongshan Dist.
Taipei City, 10462
Taiwan

Re: K242924
Trade/Device Name: OPXION Optical Skin Viewer (OPXSV1-01F)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: May 20, 2025
Received: May 22, 2025

Dear Ming-Yie Jan:

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,

Jessica Carr -S

Jessica Carr, PhD
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)*

K242924

Device Name

OPXION Optical Skin Viewer (OPXSV1-01F)

Indications for Use *(Describe)*

OPXION Optical Skin Viewer is a non-invasive imaging system intended to be used for real-time visualization of the external tissues of the human body. The two-dimensional, cross-sectional, three-dimensional, and en-face images of tissue microstructures can be obtained.

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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OPXION Tech. Incorporation

510(k) SUMMARY

This 510 (K) summary is being submitted in accordance with requirements of Title 21 CFR Section 807.92.

A.	510(k) NUMBER	K242924
B.	DATE PREPARED	June 16th, 2025
C.	SUBMITTER	OPXION Technology Inc. 22F., No. 29-2, Sec. 2, Zhongzheng E. Rd., Tamsui Dist., New Taipei City 251401, Taiwan Phone number: +886-2-8809-1666
D.	CONTACT PERSON	1. Primary Contact Title: AVP Name: Shao-Hua Huang Tel: +886-2-8809-1666 # 2101 E-mail: becket.huang@opxiontech.com 2. Official Correspondent Title: Principal Consultant Name: Ming-Yie Jan Tel: +886287858989 E-mail: FDA.sub@ruscert.net
E.	DEVICE	Proprietary Name: OPXION Optical Skin Viewer Product Code: NQQ Regulation Number: 892.1560 Regulation Name: Ultrasonic pulsed echo imaging system Device Class: Class II Review Panel: General & Plastic Surgery
F.	INDICATION(S) FOR USE	OPXION Optical Skin Viewer is a non-invasive imaging system intended to be used for real-time visualization of the external tissues of the human body. The two-dimensional, cross-sectional, three-dimensional, and en-face images of tissue microstructures can be obtained.

G.	PRIMARY PREDICATE DEVICE	Proprietary Name:	VivoSight Topical OCT System
		Product Code:	NQQ
		Regulation Number:	892.1560
		Regulation Name:	Ultrasonic pulsed echo imaging system
		510(k) Number:	K093520
		510(k) Submitter:	Michelson Diagnostics Ltd
		Device Class:	Class II
		Review Panel:	General & Plastic Surgery

H. DEVICE DECRIPTION

OPXION Optical Skin Viewer is composed of two parts consisting of a handheld probe and a mainframe, connected by an optical fiber cable. The device comes with three accessories: a USB 3.0 cable, a power adapter, and a power cord. The Optical Skin Viewer needs to be connected to a laptop or a personal computer.

I. COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICES

OPXION Optical Skin Viewer and predicate device K093520 are:

1. Same intended use/ indication(s) for use
2. Same intended population
3. Same mode of action
4. Same method of use
5. Same duration of use
6. Different technical characteristics
7. Different physical characteristics design

The OPXION Optical Skin Viewer and the predicate device, VivoSight Topical OCT System (K093520), share the same intended use and have similar technological characteristics. They both use Optical Coherence Tomography (OCT) technology to create high-resolution real-time cross-sectional and enface images of tissue microstructure. Two devices utilize near-infrared light to produce OCT images with comparable axial and lateral resolutions. The differences in technical characteristics are based on the principle of design for each device. They are designed to meet the intended use of devices to deliver the performance. Those differences do not raise any new or different concerns about safety and effectiveness.

Therefore, **OPXION Technology Inc.** concludes that **OPXION Optical Skin Viewer** is substantially equivalent to predicate devices regarding indications for use, design, and testing results, without raising any safety and efficacy risks or concerns.

B. Substantial Equivalence Comparison Table-Basic Information

Element of Comparison	Proposed Device OPXION Optical Skin Viewer	Predicate Device VivoSight Topical OCT System K093520	Comparison
Product Code	NQQ	NQQ	Same
Intended Use/Indications for Use	OPXION Optical Skin Viewer is a non-invasive imaging system intended to be used for real-time visualization of the external tissues of the human body. The two-dimensional, cross-sectional, three-dimensional, and en-face images of tissue microstructures can be obtained.	VivoSight is a Multi-Beam Optical Coherence Tomography (OCT) system indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body.	Same
Technology	Optical Coherence Tomography	Optical Coherence Tomography	Same
Near-Infrared Wavelength	Yes	Yes	Same
Light Source Center Wavelength	840 nm	1305 nm	Different
Lateral Resolution (Horizontal Optical Resolution)	10 µm	< 7.5 µm	Different
Axial Resolution (Vertical Optical Resolution)	7.5 µm	< 10 µm	Different
Maximum scan Range	5mm x 5mm	5mm x 5mm	Similar
Axial Scanning Range	Up to 2mm	Up to 2mm	Same
Scan time	25 fps	>6fps	Different

Element of Comparison	**Proposed Device** OPXION Optical Skin Viewer	**Predicate Device** VivoSight Topical OCT System K093520	**Comparison**
Optical Radiation Safety	Class 1 Laser	Class 1 Laser	Same
Energy output	Superluminescent diode, 840 nm, 6 mW	Santec HSL-2000-11 wide sweep laser, ≥25 mW	Different
Power Supply	100-240V, 50-60 Hz	110-132 V, 50-60 Hz	Different
Weight and dimensions	285mm × 135mm × 193mm 2.1 kg	650 x 700 x 1650 mm 105 kg	Different

Discussion on Technical Characteristics Difference:

Difference in central wavelength and bandwidth: Both devices use near-infrared light sources, but there is a slight difference in the spectral range. The VivoSight Topical OCT System has a central wavelength of 1305 nm with a bandwidth of 150 nm, while the OPXION Optical Skin Viewer has a central wavelength of 840 nm with a bandwidth of ~45 nm. The specifications of devices are in the near-infrared light range without raising extra concerns on the safety of use. The spectral range of OPXION Optical Skin Viewer is also commonly used for clinical ophthalmology devices with illustrating the safety of 840-nm spectral range approved.

Difference in light source nature: The OPXION Optical Skin Viewer uses a semiconductor superluminescent diode and the VivoSight Topical OCT System uses a swept source laser. This difference does not affect the safety of use but may impact factors such as cost, system size, and power consumption.

Difference in light source power: The lower the power of the light source, the less impact it has on the skin. OPXION Optical Skin Viewer have a light source output power of approximately 6 mW, while the VivoSight Topical OCT System uses a high-power sweep source laser with a power of 25 mW. In comparison, OPXION Optical Skin Viewer have a relatively safer light power level with an effective perfiormace.

Difference in system size: OPXION Optical Skin Viewer has smaller reduced size and less weight with a portable feature. The difference in system size does not affect the safety of use and efficacy.

J. SUMMARY OF PERFORMANCE DATA

The following performance data were provided to demonstrate the safety and efficacy of **OPXION Optical Skin Viewer**:

Standards	**Test Results**
IEC 62304	PASS
IEC 60601-1: 2005/A1:2012/A2:2020	PASS
EN 60601-1:2006+A2:2021	PASS
ANSI AAMI ES60601-1:2005/A2:2021 IEC	PASS
60601-2-22:2007 +A1:2012(3.1)	PASS
IEC EN 60825-1	PASS
ASTM D4169-22	PASS
ISO 10993-5:2009	PASS
ISO 10993-10:2010	PASS
IEC 62366:2007+AMD1:2014	PASS
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020	PASS

K. Performance Testing Summary

The study was conducted to evaluate the performance of the OPXION Optical Skin Viewer. The primary objective was to assess the device's ability to capture high-resolution images of skin across a diverse patient population, including variations in age, gender, and anatomical skin location.

Study Design

The evaluation involved scanning each target area in three sessions of 20 seconds each, for a total scanning duration of 60 seconds per site. The study included three subjects with healthy skin and five subjects with diseased skin conditions.

Skin Conditions Evaluated

- Healthy skin: Scanned across different anatomical locations and demographic profiles (age and gender).
- Diseased skin: Conditions included rosacea, acne scars, and psoriasis affecting various anatomical sites.

Acceptance Criteria

Image quality was confirmed and accepted by a qualified medical professional.

Data Collection Parameters

The study recorded the following parameters for each subject:

- Demographics: Gender and age
- Anatomical site of scanning
- Imaging results: 2D images, full-depth en-face images, and en-face images at different depths

Results
The OPXION Optical Skin Viewer demonstrated consistent performance in producing images of a quality that is substantially equivalent to that produced by the cited predicate device. The device successfully displayed anatomical features of skin.

No adverse events or safety concerns were reported. The scanning process was well-tolerated by all subjects.

Summary
The OPXION Optical Skin Viewer is a safe and effective clinical imaging device capable of generating two-dimensional, cross-sectional, three-dimensional, and en-face images of external tissue microstructure. Its non-invasive nature, and ability to image skin support its potential utility.

L. SUBSTANTIAL EQUIVALENCE CONCLUSION

Based upon the information presented, **OPXION Technology Inc.** concludes that the **OPXION Optical Skin Viewer** is substantially equivalent to the predicate device regarding indications for use, design, and testing results, without raising any new safety and efficacy risks or concerns.