Wingderm Electro-Optics Ltd.
℅ Ray Wang
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.,
Fangshan District
Beijing, 102401 CN

Re: K192350
Trade/Device Name: Medical Non-Ablative Fractional Laser Systems
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: ONG
Dated: August 21, 2019
Received: August 29, 2019

Dear Ray Wang:

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,

Colin Kejing Chen
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192350

Device Name
Medical Non-ablative Fractional Laser Systems (Model: WFB-01)

Indications for Use *(Describe)*
The Medical Non-ablative Fractional Laser Systems (Model: WFB-01) is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

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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Tab #3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192350

1. Date of Preparation

   04/26/2020

2. Sponsor

   Wingderm Electro-Optics Ltd.

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Medical Non-ablative Fractional Laser Systems
Common Name: Medical Non-ablative Fractional Laser Systems
Model(s): WFB-01

Regulatory Information:
Classification Name: Powered laser surgical instrument with microbeam\fractional output
Classification: 2;
Product Code: ONG;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Intended Use Statement:
The Medical Non-ablative Fractional Laser Systems (Model: WFB-01) is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

5. Device Description

The Medical Non-ablative Fractional Laser Systems (Model: WFB-01) is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.
The Medical Non-ablative Fractional Laser Systems (Model: WFB-01) includes three main parts, Main Console, Connector and Scan Handpiece.
The main console is used for system control, such as control of user interface, power on/off and other functions, and also used as holder for other components.
The Connector is used to connect with accessories or power supplier, such as foot switch, pipeline holder, cold air device etc.
The Scan Handpiece is used to provide laser emission and graphic scanning functions. It provides three scan heads (AccuTip, EffiTip, GrowTip) for treatment areas.

6. Identification of Predicate Device

Predicate Device:
510(k) Number: K170060
Product Name: M22 And Resurfx Systems
Manufacturer: Lumenis, Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI/ANSI/ES 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22 Edition 3.1 2012-10, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment.
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2014 , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- Performance Testing for Energy Output Accuracy.

8. Clinical Test Conclusion

No Clinical Test conducted.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K170060	Remark
Product Code	ONG	GEX, ONF, ONG	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Intended Use	The Medical Non-ablative Fractional Laser Systems (Model: WFB-01) is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.	ResurFX module and handpiece, with wavelength of 1565 nm, is indicated for Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue	SAME
Prescription/ OTC	Prescription Use	Prescription Use	SAME

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device K170060	Remark
Wavelengths	1550 nm	1565 nm	SAME
Fluence	Up to 70 mJ per Micro-beam	Up to 70 mJ per Micro-beam	SAME
Laser Power	15 W	15 W	SAME
Dot Density (Dot/cm^2)	500	Up to 500	SAME
Laser Beam Diameter	110 um	110 um	SAME
Inter-beam spacing	0.4 mm – 1.0 mm	0.4 mm – 1.0 mm	SAME
Beam diameter variability	Fixed	Fixed	SAME
Pulse Duration	10 ms	10 ms	SAME
Type of laser	Er:Glass	Er:Glass	SAME
Tip treatment Area	AccuTip: 10mmX10mm， EffiTip: 20mmX20mm GrowTip: 10mmX20mm	18mm SapphireCool Tip 18mm Precision Tip	Analysis
Scanning shapes	Rectangle, Hexagon, Ellipse, Triangle, Circle	Line, square, rectangle, circle, donut, hexagon, vertical line, and vertical rectangle	Analysis

Difference Analysis:

The design and technological characteristics of the subject device is basically similar to the predicate device chosen. There are minor differences between the devices including Treatment Area and Scanning shapes. These two specifications are only for different area but not affects the treatment power (fluence). So, there is no deleterious effect on safety and effectiveness due to the differences, and these minor

differences do not influence the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness. Therefore, the subject device is substantially equivalent to the Predicate device.

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device K170060	Remark
Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Performance Test	Comply with IEC 60601-2-22 and IEC 60825-1	Comply with IEC 60601-2-22 and IEC 60825-1	SAME
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SAME
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SAME

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.