



February 6, 2026

Quantel Medical  
% Maureen O'Connell  
President  
O'Connell Regulatory Consultants, Inc.  
44 Oak Street  
Stoneham, Massachusetts 02180

Re: K251507  
Trade/Device Name: INTEGRE LIO  
Regulation Number: 21 CFR 886.4390  
Regulation Name: Ophthalmic Laser  
Regulatory Class: Class II  
Product Code: HQF  
Dated: December 30, 2025  
Received: December 30, 2025

Dear Maureen O'Connell:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**CLAUDINE H. KRAWCZYK -S**

Claudine Krawczyk

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

## Indications for Use

510(k) Number (if known)  
K251507

Device Name  
INTEGRE LIO

Indications for Use (Describe)

The INTEGRE LIO is indicated to be used in ophthalmic laser procedures including retinal photocoagulation.

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****Quantel Medical  
INTEGRE LIO****Submission Sponsor**

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Date Prepared: February 6, 2026

**Trade Name of Device**

INTEGRE LIO

**Common or Usual Name**

Ophthalmic laser

**Classification Name**

Ophthalmic laser

**Product Codes:**

HQF

**Device Classification**

Class II  
21 C.F.R. §886.4390

**Predicate Device(s)**

Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator cleared in K201623

### Device Description

The INTEGRE LIO is a laser photocoagulator using visible green diode laser (532nm) technology and provide a compact design to be incorporated in a lightweight headset worn by the physician.

The INTEGRE LIO is composed of:

- a battery powered headset based on an indirect ophthalmoscope including a laser enclosure and a Head-Up Display (HUD)
- a wireless battery powered footswitch.

INTEGRE LIO is controlled by the wireless footswitch that allows the physician to set the desired parameters for treatment. The physician uses the headset to locate the area to be treated and, after setting the appropriate parameters, targets the desired tissue utilizing a visible red aiming beam. The physician presses the footswitch to deliver therapeutic green laser light to the targeted tissue. In case the battery is discharged, and the user needs to continue treatment, there is a cable available that connects the footswitch to the headset and an external power supply to connects the footswitch to an electrical outlet.

The INTEGRE LIO includes laser safety filters that will prevent a laser beam reflection to user's eye. The laser unit must be used with a focusing lens which allows retinal visualization. Ancillary personnel must wear appropriate laser safety eyewear to protect their eyes from laser beam

### Indications for Use

The INTEGRE LIO is indicated to be used in ophthalmic laser procedures including retinal photocoagulation.

### Summary of Technological Characteristics Compared to Predicate Device

The following is a tabular presentation of the INTEGRE LIO compared with the predicate device which is the Norlase Laser Indirect Ophthalmoscope (LIO) Photocagulator cleared in K201623.

#### INTEGRE LIO Substantial Equivalence

	<b>Predicate Device Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator</b>	<b>Subject Device INTEGRE LIO K251507</b>	<b>Comparison</b>
Intended Use	The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator is intended to be used in ophthalmic laser procedures.	The INTEGRE LIO is intended to be used in ophthalmic laser procedures.	Substantially equivalent

	<b>Predicate Device Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator</b>	<b>Subject Device INTEGRE LIO K251507</b>	<b>Comparison</b>
Indications for Use	The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator is indicated to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.	The INTEGRE LIO is indicated to be used in ophthalmic laser procedures including retinal photocoagulation.	Substantially equivalent. Both devices (subject device and the predicate) are indicated to be used in ophthalmic laser procedures including retinal photocoagulation. The only difference between subject device and the predicate is that INTEGRE LIO (subject device) is not indicated for iridotomy and trabeculoplasty. However, this does not impact the substantial equivalence because indications for use for the INTEGRE LIO (subject device) are within the indications for use for the predicate device.
Manufacturer	Norlase Aps	QUANTEL MEDICAL	N/A
510k number	K201623	/	N/A
Regulation medical specialty	Ophthalmic	Ophthalmic	Substantially equivalent
Review panel	Ophthalmic	Ophthalmic	Substantially equivalent
Product code	HQF	HQF	Substantially equivalent
Regulation number	886.4390	886.4390	Substantially equivalent
Classification	II	II	Substantially equivalent
<b>Treatment beam</b>			
Laser type	Laser diode	Laser diode	Substantially equivalent

	<b>Predicate Device Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator</b>	<b>Subject Device INTEGRE LIO K251507</b>	<b>Comparison</b>
Wavelength	520 nm	532 nm	Substantially equivalent  The laser 532nm and 520nm are both green lasers. The mechanism of action for both lasers is photocoagulation (laser energy is absorbed by retinal pigments and converted to thermal energy. The subsequent temperature rises in the targeted tissue and causes denaturation of tissue proteins and coagulative necrosis).
Laser mode	Continuous wave (CW)	Continuous wave (CW)	Substantially equivalent
Laser classification US FDA CDRH	Class IV	Class IV	Substantially equivalent
European laser classification IEC 60825	Class 4	Class 4	Substantially equivalent
Maximum power output	1000mW	1000mW	Substantially equivalent
Pulse duration	10 ms – 1000 ms	10 ms – 1000 ms	Substantially equivalent
Spot size	1.1 mm (in air)	1.1 mm (in air)	Substantially equivalent
Beam divergence	31 mrad	31 mrad	Substantially equivalent
<b>Aiming beam</b>			
Aiming beam type	Laser diode	Laser diode	Substantially equivalent
Wavelength	635 nm	635 nm	Substantially equivalent
Power output	< 1 mW continuously variable	< 1 mW continuously variable	Substantially equivalent
<b>Illumination</b>			
Type	Dimmable white light LED	Dimmable white light LED	Substantially equivalent

The intended use of the INTEGRE LIO is the same as the intended use of the predicate device and the indications for use are also nearly identical. Both devices are prescription devices for use by trained healthcare providers. The INTEGRE LIO has the same technological characteristics as

the predicate device as described in Substantial Equivalence table. Both lasers are photocoagulators intended to be used for ocular treatment including retinal photocoagulation. The laser source for both devices is diode (the same type of laser). Both lasers that have been evaluated with recognized consensus standards and found to be safe and both devices comply with applicable electrical safety and electromagnetic compatibility standards.

### **Performance Data**

Non-clinical testing was performed to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device.

- IEC 60601-1 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60601-2-22 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 Safety of laser products-Part 1: Equipment classification and requirements
- ISO 15004-2 Ophthalmic instruments - Fundamental requirements and test methods -Part 1: Light hazard protection
- ANSI Z80.36-2021 Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
- Software verification and validation activities were performed per FDA software guidance ([Content of Premarket Submissions for Device Software Functions](#)) to ensure the device performed as intended. Enhanced software documentation was provided.
- Cybersecurity documentation was provided per FDA's cybersecurity guidance ([Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions](#)).
- Human factors testing was performed per FDA's human factors guidance ([Applying Human Factors and Usability Engineering to Medical Devices](#)).
- Hardware verification was performed.

### **Conclusion**

Quantel Medical believes that the INTEGRE LIO described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device, the Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator cleared in K201623.