IPG Medical
% Connie Hoy
Managing Partner
Hoy and Associates
1830 Bonnie Way
Sacramento, California 95825

Re: K233344
Trade/Device Name: Regenalase Laser System
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: April 21, 2024
Received: April 22, 2024

Dear Connie Hoy:

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,

for Yan Fu -S Digitally signed by Yan Fu -S Date: 2024.05.28 13:10:42 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233344

Device Name
Regenalase Laser System

Indications for Use *(Describe)*

1550nm laser:

Indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue, including meniscus cartilage, in conjunction with an imaging modality for medical specialties including: General Surgery, Orthopedics, Podiatry, Arthroscopy and Spinal Surgery.

980nm laser:

Indicated for use to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

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
K233344

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

Date of Preparation: 05/24/2024

Manufacturer Identification:

IPG Medical
225 Cedar Hill Street
Marlborough, MA 01752
Phone: 508-506-2800
Establishment Registration # 3020221089
Contact Person: Alexander Vybornov

Device Identification:

Device Trade Name:	Regenalase Laser System
Device Common Name:	Laser Instrument for Use in General Surgery
Classification Name:	Laser Instrument, Surgical, Powered
Classification Number:	21 CFR 878.4810
Product Code:	GEX
Device Class:	Class II
Review Panel:	General and Plastic Surgery

In addition, there is a 980 nm diode laser with the product code ILY. This laser is Class II exempt.

Identification of Predicate Device for the 1550 nm laser:

Trade Name	Manufacturer	510(k)
neoV1470 Diode Laser	G.N.S. neoLaser Ltd.	# K152722

Device Description

The Regenalase is a portable console that houses a fiber laser operating at 1550 nm wavelength and a diode laser operating at 980 nm wavelength. The system utilizes a wired one-pedal footswitch for hands-free laser activation. The console consists of the

1550 nm laser module, the 980 nm laser module, control electronics, optical module, air cooling, and a touch screen display.

The laser energy for the 1550 nm laser is delivered via previously cleared commercially available laser fibers. The fibers come in two different sizes.

The 980 nm laser is used with a fiber delivery system, consisting of the Universal Stage One handpiece and four different attachments.

Indications for Use:

1550 nm laser:

Indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue, including meniscus cartilage, in conjunction with an imaging modality for medical specialties including: General Surgery, Orthopedics, Podiatry, Arthroscopy and Spinal Surgery.

980 nm laser:

Provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

Technological Comparison to Predicate Device:

	Regenalase (Subject Device)	neoV1470 (Predicate Device) K133006	Different/Same
Wavelength	1550 nm	1470 nm	Different
Output Modes	Pulsed, Single Pulse and CW	Pulsed, Single Pulse and CW	Same
Max Power (W)	0.8 to 10 adjustable	1 to 10 adjustable	Comparable
Pulse Duration	10 ms to 2 s	0.1 ms to 30 s	Different
Laser Beam Delivery	Fiber (400 μm & 600 μm)	Fiber (400 μm & 600 μm)	Same
Pilot Beam wavelength	480 - 530 nm	532 nm	Different
Dimensions	11” x 11” x 11’’	8”x 8”x 4”	Different
Weight	12 lbs.	8 lbs.	Different

Difference in Wavelength

The Subject device’s laser wavelength is 1550 nm and the Predicate device’s laser wavelength is 1470 nm. Both wavelengths are utilized in the industry for the same purpose: to heat the water contained in the tissue. Water is the predominant

chromophore in soft tissues that absorbs light at these wavelength range to produce heat.

To validate that the tissue effects produced by the 1470 nm and 1550 nm laser wavelengths are substantially equivalent, IPG Medical has conducted an ex vivo study comparing the thermal damage that could be induced by the two lasers side-by-side on three different tissue types for the best-case, realistic-case, and worst-case energy deposition from the two devices. The results show that the two devices produced comparable thermal damage.

Difference in Pulse Duration

The Subject device's pulse durations are in the range between 10 ms and 2 s. The Predicate device's range is between 0.1 ms and 30 s. The Subject device's pulse durations fall within the range of the Predicate device's pulse durations. All possible combinations of power and pulse duration of the Subject device are a subset of all possible combinations of power and pulse duration of the Predicate device. Therefore, there are no new additional questions of safety and effectiveness raised since all the Predicate device's possible combinations of power and pulse duration are equivalent to those of the Predicate device.

Difference in Pilot Beam wavelengths

The Subject device differences in pilot beam wavelengths, both being visible, do not raise any different concerns for safety.

Non-Clinical Testing

Risk analysis management

Risk management was performed according to ISO 14971 Third Edition 2019-11 Medical Devices –Application of risk management to medical devices and the FDA Guidance Document.

Electrical safety and electromagnetic compatibility

The device conforms to the following standards.

IEC 60601-1:2005 C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

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.

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 Edition 2.0 2007-03 Safety of Laser Products- Part 1Equipment Classification, and requirements [including Technical Corrigendum 1(2008), Interpretation Sheet 1, (2007), Interpretation Sheet 2(2007)

Software

Software verification and validation testing was conducted and documentation provided as recommended by the FDA's "Guidance for the Content of Premarket Submissions Contained in Medical Devices" and in ANSI/AAMI/IEC 62304:2006/A1:2016 Medical Device software- Software life cycle processes-including Amendment 1(2016). Device software verification and validation results were found acceptable for software release.

Human Factors

Human Factors of the laser system was confirmed using ANSI/AAMI/IEC 1:2015+AMD1 2020 (Consolidated Text) Medical Devices Part 1 Application of Usability engineering to medical devices including Amendment 1 and the results found to be acceptable.

Biocompatibility

Patient Contacting Materials

Biocompatibility testing was conducted to confirm that the proposed patient contact attachments meet all the applicable biocompatibility requirements in compliance with ISO 10993-1 and the FDA Guidance "Use of the International Standard ISO 10993-1 'Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process"

The results of the tests indicated that all success criteria were met with no issues.

Bench Testing Data

The Regenalase Laser system performance characteristics were evaluated through testing and analysis of laser power output and beam quality where applicable. The ability of the new device to withstand variant operation, storage and transportation conditions were tested. The system testing (energy measurements, safety controls, emission indicator, fiber and aiming beam) was also completed. Testing shows that the device delivers set energy parameters within specifications and performs as intended.

Thermal Performance Evaluation

Thermal damage was measured in three ex vivo tissue samples heated to 37 ^{0}C due to the best-case, realistic-case and worst-case energy deposition from the subject and predicate devices. The data show that the induced damage was comparable between the subject and predicate devices for comparable energy deposition.

Clinical Performance Data

Clinical trials were not deemed necessary as the new device is using similar technology and intended use as the Predicate device.

Summary of Substantial Equivalence

The Regenalase Laser System and the Predicate device have the same intended use as surgical lasers with similar indications for use. The Regenalase Laser System presents similar technological characteristics as its Predicate device, including laser type, similar wavelength, device design, waveforms and pulsed mode characteristics and fiber size. Although there may be minor differences in the details of the device design, the differences do not raise different questions of safety or effectiveness.

Conclusions

Comparison between the Regenalase Laser System and the predicate device shows that the Regenalase Laser System is as safe and effective as the predicate device. The subject device Regenalase Laser System has similar intended use and indications for use, technological characteristics, the same principle of operation, and similar performance as the predicate device.