September 1, 2021

CeramOptec GmbH
℅ Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K210951
Trade/Device Name: Leonardo Mini Blue
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: March 28, 2021
Received: March 30, 2021

Dear Daniel Kamm:

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,

Purva Pandya
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)*
K210951

Device Name
Leonardo Mini Blue 445nm Laser

Indications for Use *(Describe)*
The Leonardo Mini Blue 445nm Laser is intended for incision, excision, vaporization, ablation, hemostasis 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.

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510(k) Summary: 510(k) Number K210951

CeramOptec GMBH
Siemensstrabe 44
Bonn Nordrhein-Westfalen, Bonn, Germany D-53121
Registration Number: 3003340844
Phone Number: +49 (228) 97 967 – 0
Date Prepared: August 31, 2021
Contact: Dr. Roland Dreschau, Director

1) **Identification of the Device:**
   Trade/Device Name: Leonardo® Mini Blue 445nm Laser
   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

2) **Equivalent legally marketed device: K192272, A.R.C. Laser GmbH**
   Trade/Device Name: Wolf 445nm
   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

3) **Reference Devices (Sterile Single Patient Use Fiberoptic Probes)**
   Biolitec Medical Devices, Inc.:
   MegaBeam ENT Probe: K113858.,
   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
   and
   Biolitec Medical Devices, Inc.:
   MegaBeam 400 Micron Forward fire: K113709.
   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

4) **Indications for Use: The Leonardo Mini Blue 445nm Laser is intended for incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue.**

5) **Description of the Device**: The laser family LEONARDO® Mini Blue is a laser system with functions and ergonomics specially developed for medical applications. A control panel is used to set treatment

parameters, such as laser power. User-friendly menu navigation ensures a reliable operation while allowing physicians to concentrate on the essential aspects of treatment. The fiber-coupled semiconductor laser diodes convert electrical energy to coherent laser radiation with the wavelength of 445 nm (aiming beam 635 nm). A beam transporting system delivers this energy to affected surfaces and organs. Depending on the model, the LEONARDO® Mini Blue laser has the following maximum laser output power:
LEONARDO® Mini Blue: 10W@445nm
LEONARDO® Mini Blue is available as a single-wavelength device with 445 nm. All LEONARDO® Mini Blue laser can be operated in continuous mode. Additional special treatment modes for specific treatment procedures or in combination with corresponding application fibers are available, depending on the configuration of the unit. For safety reasons, the LEONARDO® Mini Blue laser is equipped with a system for automatic recognition of the optical fibers used. Application fibers from CeramOptec have coding for communicating with the laser device.

Substantial Equivalence Chart

Characteristic	A.R.C. Laser GmbH Device Wolf 445nm K192272	CeramOptec GMBH Leonardo® Mini Blue 445nm Laser
Indications for Use	The Wolf 445 nm is intended for incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue.	The Leonardo Mini Blue 445nm Laser is intended for incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue. SAME
Photo		
Display	Touch Screen	Touch Screen SAME
Mode	Diode Laser	Diode Laser SAME
Laser power	0.5 W up to 10 W	Up to 10 W SAME
Laser type	Diode Laser	Diode Laser SAME
Wavelength	445 nm	445 nm SAME

Characteristic	A.R.C. Laser GmbH Device Wolf 445nm K192272	CeramOptec GMBH Leonardo® Mini Blue 445nm Laser
Aiming beam	532 nm	635 nm Both predicate and proposed device aiming beams are within the readily visible spectrum. No adverse safety or effectiveness impact.
Aiming beam power	≤ 5 mW	Max. 4 Mw. Comparable. No adverse safety or effectiveness impact.
Laser Class	4	4
Operation mode	Pulsed, Continuous Wave (CW)	Pulsed, Continuous Wave (CW) SAME
Pulse length/ duration	≤ 4 Watt: 1 ms to 45 sec and CW > 4 Watt: 1 ms to 60 ms	10 Watt: 10 ms to 1 sec and CW. Useful range for the indications. No adverse safety or effectiveness impact.
Pulse frequency	≤ 4 Watt: 0.01 Hz to 500 Hz and SP > 4 Watt: 0.02 Hz to 6.6 Hz and SP	10 Watt: 0.5Hz – 50Hz Useful range for the indications. No adverse safety or effectiveness impact.
Cooling	Air	Internal Fan. No adverse safety or effectiveness impact.
Main power Supply	100-240 V~, 47-63 Hz, 1.06-0.45 A	Mains operated OR Li-ion rechargeable battery. No adverse safety or effectiveness impact.
Dimensions of system	H 10.06 cm (3.9 inches), W 20.3 cm (7.9 inches), 23.9 cm (9.4 inches)	H 6 cm, W 9 cm, L 21,5 cm. SMALLER. No adverse safety or effectiveness impact.
Weight	2.8 kg (6.17 pounds)	0.960kg (without batteries) 2x 0.045kg (battery weight) LIGHTER WEIGHT No adverse safety or effectiveness impact.

6) The technological characteristics are substantially the same, so there are no issues impacting safety and effectiveness. Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new device is as safe and effective as the predicate device.

7) **Summary of non-clinical testing**:
Firmware was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.* Software validation documents were provided for a moderate level of concern.
This device complies with the applicable portions of the standards listed below:

21 CFR Part 1040 PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

EN 1041:2008 Information Supplied By The Manufacturer Of Medical Devices

ISO 14971: 2007 Medical devices — Application of risk management to medical devices FDA # 5-40

IEC ISO 15223-1:2016 (Corrected Version 2017-03) Medical devices — Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements FDA # 5-117

IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

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 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-2-22: 2007+A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment FDA # 12-268

IEC 62304: 2006 Medical device software - Software life cycle processes

IEC 62366-1:2007+A1:2014 Medical devices - Part 1: Application of usability engineering to medical devices FDA # 5-114

IEC 60825-1: 2007 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)] FDA # 12-273

The IEC standards testing was conducted by an accredited testing laboratory “EZU”.

8) **Summary of clinical testing:** Clinical testing was not required to establish substantial equivalence.

9) **Conclusion: After analyzing bench and clinical tests, it is the conclusion of CeramOptec GMBH that the new CeramOptec GMBH Leonardo® Mini Blue 445nm Laser is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**