July 14, 2025

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

Re: K250504
Trade/Device Name: Leonardo Duster
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: February 20, 2025
Received: February 20, 2025

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 (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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.07.14 14:22:56 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250504

Device Name
Leonardo Duster

Indications for Use *(Describe)*
The Leonardo® Duster is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology
• Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH] • Laser Resection of the Prostrate (LRP) • Laser Enucleation of the Prostate (LEP) • Laser Ablation of the Prostate (LAP) • Transurethral Incision of the Prostate (TUIP) • Condylomas • Urethral/ureteral structures • Lesions of external genitalia • Bladder neck incisions (BNI) • Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors • Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi •Treatment of distal impacted fragments remaining in the ureters following lithotripsy. Lithotripsy and

Percutaneous Urinary Lithotripsy Indications
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones • Endoscopic fragmentation of renal calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Appendectomy • Polyps • Biopsy • Gall Bladder calculi • Biliary/Bile duct calculi • Ulcers • Gastric ulcers • Duodenal ulcers • Non Bleeding Ulcers • Pancreatitis • Haemorrhoids • Cholecystectomy • Benign and Malignant Neoplasm Gynecology •Angiodysplasia • Colorectal cancer • Telangiectasias • Telangiectasias of the Osler-Weber-Renu disease • Vascular Malformation • Gastritis • Esophagitis • Esophageal ulcers • Varices • Colitis • Mallory-Weiss tear • Gastric Erosions

Gynecology
Open, endoscopic (including hysteroscopic) and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) 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 K250504

CeramOptec GMBH
Siemensstrabe 44
Bonn Nordrhein-Westfalen, Germany D-53121
Telephone +49 228 979670
Date Prepared: July 10, 2025
Contact: Dr. Roland Dreschau, Director
Email Roland.Dreschau@biolitec.com

1) **Identification of the Device:**
   Trade/Device Name: Leonardo® Duster
   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: K242191 SOLTIVE™ Laser System**
   Trade/Device Name: SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)
   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 Reusable and Single Patient Use Fiberoptic Probes)**
   Biolitec Medical Devices, Inc.:
   MegaBeam Reusable Fiber Optic Delivery System: K113688
   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 Fiber Optic Delivery System with Additional Tips & Handpiece: 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® Duster is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery. Urology
   • Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
   • Laser Resection of the Prostrate (LRP)
   • Laser Enucleation of the Prostate (LEP)

• Laser Ablation of the Prostate (LAP)
• Transurethral Incision of the Prostate (TUIP)
• Condylomas
• Urethral/ureteral strictures
• Lesions of external genitalia
• Bladder neck incisions (BNI)
• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
•Treatment of distal impacted fragments remaining in the ureters following lithotripsy.

Lithotripsy and Percutaneous Urinary Lithotripsy Indications
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones
• Endoscopic fragmentation of renal calculi
• Treatment of distal impacted fragments
of steinstrasse when guide wire cannot be passed.

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Appendectomy
• Polyps
• Biopsy
• Gall Bladder calculi
• Biliary/Bile duct calculi
• Ulcers
• Gastric ulcers
• Duodenal ulcers
• Non Bleeding Ulcers
• Pancreatitis
• Haemorrhoids
• Cholecystectomy
• Benign and Malignant Neoplasm Gynecology •Angiodysplasia
• Colorectal cancer
• Telangiectasias
• Telangiectasias of the Osler-Weber-Renu disease
• Vascular Malformation
• Gastritis
• Esophagitis
• Esophageal ulcers
• Varices
• Colitis
• Mallory-Weiss tear
• Gastric Erosions
Gynecology
Open, endoscopic (including hysteroscopic) and laparoscopic gynecological surgery (incision, excision, resection, ablation,

vaporization, coagulation and hemostasis) of soft tissue.

5) **Description of the Device**: All variants of the laser family LEONARDO® Duster are laser systems with functions and ergonomics specially developed for med ical applications. A touchscreen is used to set treatment parameters, such as Power in Continuous mode, Pulse energy (J) and Frequency (Hz) with Pulse width options in Pulse mode. User-friendly menu navigation and microprocessor-supported control ensure reliable operation while allowing physicians to concentrate on the essential aspects of treatment. The Thulium doped fiber laser module produce a coherent laser radiation with the wavelength of 1940nm±3nm (aiming beam 525nm +/-10nm). An optical fiber delivers this energy to affected surfaces and organs. All fields of application are listed in the indications for use statement.
The subject model LEONARDO® Duster laser has a maximum laser output power of 60W. @ 1940nm The LEONARDO® Duster is available only as a single-wavelength device with 1940nm. All LEONARDO® Duster lasers can be operated in two basic modes, CONTINUOUS or PULSE MODE. Two application modes are available which defines the intended use of the device: Lithotripsy and Other. For safety reasons, the LEONARDO® Duster laser is equipped with a system for automatic recognition of the used optical fibers. Application fibers from CeramOptec are RFID encoded for communicating with the laser device. Reusable fiber probes are available in 6 different sizes. They are initially EO sterilized. Subsequent sterilization is via autoclave. Single patient use fiber probes come in 7 different sizes. They are initially EO sterilized.

6) **The comparison between the overall specifications of predicate device and the subject device is shown in Table 1, below.**

Table 1 Substantial Equivalence Chart

Characteristic	Olympus Surgical Technologies America K242191 SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)	CeramOptec GMBH Leonardo® Duster
Indications for Use	The SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery. **Urology** • Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH] • Laser Resection of the Prostrate (LRP) • Laser Enucleation of the Prostate (LEP) • Laser Ablation of the Prostate (LAP) • Transurethral Incision of the Prostate (TUIP) • Condylomas • Urethral/ureteral strictures • Lesions of external genitalia	The Leonardo® Duster is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery. **Urology** • Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH] • Laser Resection of the Prostrate (LRP) • Laser Enucleation of the Prostate (LEP) • Laser Ablation of the Prostate (LAP) • Transurethral Incision of the Prostate (TUIP) • Condylomas • Urethral/ureteral strictures • Lesions of external genitalia

Characteristic	Olympus Surgical Technologies America K242191 SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)	CeramOptec GMBH Leonardo® Duster
	• Bladder neck incisions (BNI) • Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors • Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi •Treatment of distal impacted fragments remaining in the ureters following lithotripsy. Lithotripsy and Percutaneous Urinary Lithotripsy Indications • Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones • Endoscopic fragmentation of renal calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed. **Gastroenterology** Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: • Appendectomy • Polyps • Biopsy • Gall Bladder calculi • Biliary/Bile duct calculi • Ulcers • Gastric ulcers • Duodenal ulcers • Non Bleeding Ulcers • Pancreatitis • Haemorrhoids • Cholecystectomy • Benign and Malignant Neoplasm Gynecology •Angiodysplasia • Colorectal cancer • Telangiectasias • Telangiectasias of the Osler-Weber-Renu disease • Vascular Malformation • Gastritis • Esophagitis • Esophageal ulcers • Varices	• Bladder neck incisions (BNI) • Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors • Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi •Treatment of distal impacted fragments remaining in the ureters following lithotripsy. Lithotripsy and Percutaneous Urinary Lithotripsy Indications • Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones • Endoscopic fragmentation of renal calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed. **Gastroenterology** Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: • Appendectomy • Polyps • Biopsy • Gall Bladder calculi • Biliary/Bile duct calculi • Ulcers • Gastric ulcers • Duodenal ulcers • Non Bleeding Ulcers • Pancreatitis • Haemorrhoids • Cholecystectomy • Benign and Malignant Neoplasm Gynecology •Angiodysplasia • Colorectal cancer • Telangiectasias • Telangiectasias of the Osler-Weber-Renu disease • Vascular Malformation • Gastritis • Esophagitis • Esophageal ulcers • Varices

Characteristic	Olympus Surgical Technologies America K242191 SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)	CeramOptec GMBH Leonardo® Duster
	• Colitis • Mallory-Weiss tear • Gastric Erosions **Gynecology** Open, endoscopic (including hysteroscopic) and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue.	• Colitis • Mallory-Weiss tear • Gastric Erosions **Gynecology** Open, endoscopic (including hysteroscopic) and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue. IDENTICAL INDICATIONS FOR USE
Photo		
Display	Touch Screen	Touch Screen SAME
Mode	Fiber laser	Fiber laser SAME
Laser power	60W	60W SAME
Laser type	Thulium Laser	Thulium Laser SAME
Wavelength	1940 nm	1940 nm SAME
Aiming beam	500 - 550 nm,	525 nm SAME
Aiming beam mW	≤ 5 mW	≤ 3mW +/-20%
Laser Class	4	4
Operation mode	Pulsed, Continuous Wave (CW)	Pulsed, Continuous Wave (CW) SAME
Pulse length/ duration	0.2 to 50ms	0.04 to 50ms NEARLY IDENTICAL
Pulse frequency	1 to 2500 Hz	1 to 2500 Hz SAME
Cooling	Air cooling system	Air cooling system SAME

Characteristic	Olympus Surgical Technologies America K242191 SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)	CeramOptec GMBH Leonardo® Duster
Main power Supply	100-240 Vac; 50/60 Hz; 1200 VA	100-240 Vac; 50/60 Hz; 1000 VA SAME
Dimensions of system	25.5 X 37.0 X 56.0 cm	57.7 cm (W) × 36.8 cm (D) × 37.8 cm (H) SIMILAR.
Weight	33kg	41kg SLIGHTLY HEAVIER

7) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device: The INDICATIONS FOR USE are IDENTICAL. The results of bench and standards testing indicate that the new device is as safe and effective as the predicate device.

8) **Summary of non-clinical testing**:
Firmware was validated according to the FDA Guidance: *Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff (2023).* Software validation documents were provided for a basic level of documentation. Reprocessing validation (for reusable fiber optic probes) was performed according to *Reprocessing Medical Devices in Health Care Settings: Validation Methods and* Labeling Guidance for Industry and Food and Drug Administration Staff

This device complies with the applicable portions of the standards listed below:

21 CFR 1040 PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

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

ISO 14971: 2019-12 Medical devices — Application of risk management to medical devices FDA # 5-125

IEC ISO 15223-1: 2021-07 (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 # 5-134

IEC 60601-1:2005/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) FDA # 19-49

IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests FDA # 19-36

IEC 60601-1-6:2010/AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability FDA # 5-132

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 62366-1:2015/AMD1:2020 Medical device software - Software life cycle processes FDA # 5-129

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 following standards were applied to the laser fiber probes:

Biocompatibility:
Cytotoxicity ISO 10993-5:2009
Irritation ISO 10993-10:2013
Delayed type hypersensitivity ISO 10993-10:2013
Material mediated pyrogenicity ISO 10993-11:2018
Acute systemic toxicity ISO 10993-11:2018
Allowable limits for leachable substances ISO 10993-17:2009; ISO/TS 21726:2019
Chemical characterization ISO 10993-18:2020

Sterilization:
ISO 11135:2014 + AMD. 1:2019 for the sterilization process and
EN ISO 11737-2 for the tests of sterility. T
EN 556-1: “Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 1: Requirements for terminally sterilized medical devices”

The standards testing was conducted by accredited testing laboratories.

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

10) **Conclusion: After analyzing bench, software validation, and standards compliance tests, it is the conclusion of CeramOptec GMBH that the new CeramOptec GMBH Leonardo® Duster 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.**