July 31, 2025

Lutronic Corporation
% Sean Reynolds
Senior Manager, Global Regulatory Affairs
Cynosure Inc
3/5 Carlisle Rd
Westford, Massachusetts 01886

Re: K244060
Trade/Device Name: eCO2 3D
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, GEX
Dated: July 2, 2025
Received: July 2, 2025

Dear Sean Reynolds:

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: 2025.07.31 23:56:18 -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)*
K244060

Device Name
eCO2 3D

Indications for Use *(Describe)*
The eCO2 3D Laser System with fractional handpieces is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

The eCO2 3D Laser System using the non-fractional handpieces (F100, F50, Zoom, and 500 micron tip) is also indicated for use in skin resurfacing and surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, and podiatry.

Dermatology & Plastic Surgery:
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:
* Laser skin resurfacing
* Treatment of wrinkles, rhytids and furrows
* Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement.

Dermatology. Plastic Surgery & General Surgery: Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

Podiatry:
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares.

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

#K244060

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Lutronic Corporation
Address	Lutronic Center 219, Sowon-Ro Deogyang-Gu, Goyang-Si, KR 410220
Phone number	888-588-7644
Fax number	N/A
Establishment Registration Number	3004483538
Name of contact person	Sean Reynolds Sr. Manager, Regulatory Affairs 3/5 Carlisle Road Westford, MA, 01886
Date prepared	29 July 2025
807.92(a)(2) - Name of device	
Trade or proprietary name	eCO2 3D
Common or usual name	Surgical Laser
Classification name	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.4810
Product Code(s)	GEX, ONG
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Lutronic Corporation eCO2 Plus K100610 (01/20/2011) Predicate SNJ Co. Ltd Finexel K213557 (04/12/2022) Reference
807.92(a)(4) - Device description	
	The eCO2 3D Laser System consists of a self-contained console, with a 10.6µm wavelength delivered through an articulated arm. The emitted laser beam is then irradiated to the treatment area through a handpiece and a tip connected to the handpiece The eCO2 3D is used by a trained physician for procedures requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue.

	The eCO2 3D Laser System utilizes an articulated arm to generate a laser beam with a wavelength of 10.6μm by applying patented chaos scanning technology. It radiates a micro-laser beam with an aiming beam of 520nm to the surgical area. Micro laser beams are radiated onto the treatment area, generating MAC (Micro Ablative Column), which improves the skin condition as it recovers. By changing the handpiece according to various application areas, the user can change the beam spot size to optimize the treatment effect. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different handpiece tip. The system console is the heart of the eCO2 3D Laser System and contains the Touch LCD, handpieces, system control module, and power supply module. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the Touch LCD. There are 4 casters in the console base that can be used when moving the system.
807.92(a)(5) Intended use of the device	
Indications for use	The eCO2 3D Laser System with fractional handpieces is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia. The eCO2 3D Laser System using the non-fractional handpieces (F100, F50, Zoom and 500 micron tip) is also indicated for use in skin resurfacing and surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, and podiatry. Dermatology & Plastic Surgery: The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: * Laser skin resurfacing * Treatment of wrinkles, rhytids and furrows * Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement. Dermatology. Plastic Surgery & General Surgery: Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair

	transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications. Podiatry: Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

	eCO2 3D	**eCO2 Plus K100610**	**Finexel CO2 Laser System K213557**
Indications for Use	See Indications for Use Above	See Indications for Use in Comparison Table	See Indications for Use in Comparison Table
Laser wavelength	10.6µm (=10,600 nm)	10.6µm (=10,600 nm)	10.6µm (=10,600 nm)
Medium of transmission	CO2	CO2	CO2
Laser transfer method	Articulated arm with Handpiece	Articulated arm and scanner handpiece	Articulated arm and scanner handpiece
Aiming Beam	520nm (Green) +/- 5nm	637nm	630nm-650nm
CO2 RF Module Maximum Power	40Watt at Continuous Wave (Max. 30W with surgical handpiece, Max. 40W with Fractional handpiece and Bella V handpiece)	30Watt at Continuous Wave	30/40W
Type and Degree of protection against shock	CLASS I/ B-type	CLASS I/ B-type	CLASS I/ B-type
Laser class	CLASS IV	CLASS IV	CLASS IV
User Interface	10.1inch Touch LCD Display	Touch LCD Display	Touch LCD Display
Dimensions	391mm(W) x 581mm(L) x1931mm(H)	360mm(W) x 450mm(L) x1170mm(H)	350mm(W) x 400mm(L) x 1000mm (H)
Weight (excluding the arm)	45kg	48kg	50kg
Device Cooling method	Air cooling	Air Cooling	Air Cooling
Electrical rating	Single Phase AC100~230V, 50Hz/60Hz (FUSE 250V/6.3A or 125V/6.3A), Power consumption: 550VA	Single phase AC100~240VAC (FUSE 250VAC/6.3A or 125/12.6A), 50/60Hz, Power consumption:400VA	100-120V~/220-230V~, 50/60Hz

807.92(b)(1) NON CLINICAL TESTS SUBMITTED

IEC60601-1	Medical electrical equipment - Part 1: General requirements for safety	2012+AMD2: 2020

	IEC 60601-1-2	Medical electrical equipment - Part1-2: General requirements for safety –Collateral standard: Electromagnetic compatibility - Requirements and Tests	2014/AMD1:2020
	IEC 60601-1-6:	Medical electrical equipment - Part 1-6 General requirements for basic safety and essential performance – Collateral Standard: Usability	2010+AMD1:2013+AMD2:2020
	IEC 60601-2-22	Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment	2019
	IEC 60825-1	Safety of laser products – Part 1: Equipment classification and requirements	2014
	EN ISO 14971	Medical devices -Application of risk management to medical devices	2019
	ISO/TR 24971	Medical devices-Guidance on the application of ISO 14971 (ISO/TR 24971:2020)	2020
	IEC 62366-1	Medical devices -Application of usability engineering to medical devices	2015+AMD1: 2020
	IEC 62304	Medical device software - Software life cycle processes	2006/ A1:2015
	ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing	2018
	ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	2009
	ISO 10993-10	Biological evaluation of medical devices -- Part 10: Tests for skin sensitization	2021
	ISO 10993-17	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents	2023
	ISO 10993-18	Biological evaluation of medical devices 4 Part 18: Chemical characterization of medical device materials within a risk management process 4 Amendment 1: Determination of the uncertainty factor	2020
	ISO 10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation	2021
	ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
	ISO 20471	Information Supplied by the manufacturer with medical device	2021
	ISO 15883-5	Washer disinfectors Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	2021
	ISO 15883-1	Washer-disinfectors –Part 1: General requirements terms and definitions and tests	2006/Amd 1:2014
	ISO 15883-4	Washer disinfectors Part 4: Requirements and tests for washer disinfectors employing chemical disinfection for thermolabile endoscopes	2018
	ISO 17664 1	Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi critical medical devices	2021

	ISO 11607-1	Packaging for terminally sterilized medical devices – Part1: Requirements for materials, sterile barrier systems and packaging systems	2019
	ISO 11607-2	Packaging for terminally sterilized medical devices – Part2: Validation requirements for forming, sealing and assembly processes	2019

807.92(b)(2) CLINICAL TESTS SUBMITTED

No clinical tests were performed for this submission.

807.92(b)(3) Conclusion

Based on the comparison of the technological characteristics, the specifications for the eCO2 3D are the same or a subset of the eCO2 Plus specifications. The additional tips allows the users more options in how the same energy is shaped during delivery and are similar to the reference device, Finexel. Also, the indication is the same as the predicate device, eCO2 Plus.