



Food and Drug Administration
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Cynosure, Incorporated dba Ellman
Ms. Alison Sathe
Director of Regulatory and Clinical Affairs
400 Karin Lane
Hicksville, New York 11801

July 21, 2015

Re: K150587
Trade/Device Name: Cortex 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: June 15, 2015
Received: June 17, 2015

Dear Ms. Sathe:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

For

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150587

Device Name
Cortex Laser System

Indications for Use (Describe)

The CO2 laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

The CO2 System is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery.

Dermatology, Plastic Surgery and General Surgery procedures:

- Laser skin resurfacing.
- Treatment of furrows and wrinkles.
- Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.
- Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
- Blepharoplasty.
- Site preparation for hair transplants.
- The fractional scanner is for skin resurfacing.

The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

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

This 510(K) Summary of safety and effectiveness for the Cortex Laser System is submitted in accordance with the requirements of the SMDA 1990 and FDA guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cynosure, Inc. dba Ellman
Address:	Cynosure, Inc. dba Ellman 400 Karin Lane Hicksville, NY 11801
Contact Person:	Alison Sathe
Telephone/Email/Fax:	513-658-8960 asathe@ellman.com 516-267-6750
Preparation Date:	February 20, 2015
Device Trade Name:	Cortex Laser System
Common Name:	CO2 Laser, Er:YAG Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878.4810
Legally Marketed Predicate Device(s):	Cortex Laser System K110897 DEKA SmartXide ² Laser System K133895 C02-2B3 Galaxy CO2 Laser System K133915

Device Description:

The Cortex system and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. The CO2 laser is delivered via an articulated arm that is permanently attached to the console. The Er:YAG handpiece attaches to a port on the console and contains the laser cavity in the head of the handpiece. The user interface is a touch screen located on the console. The user activates the laser emission by means of a footswitch.

Intended Use:

The CO2 laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

The CO2 System is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery.

Dermatology, Plastic Surgery and General Surgery procedures:

- Laser skin resurfacing.
- Treatment of furrows and wrinkles.
- Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.
- Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
- Blepharoplasty.
- Site preparation for hair transplants.
- The fractional scanner is for skin resurfacing.

The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

Technological Characteristics:

	Cortex Laser System ¹
Source	CO ₂
Wavelength	10.6 micron (10,600nm)
Power to tissue	0.5 - 40 W
Peak power	200 W
Repetition Rate	1 - 8 Hz / 240 Hz Super Pulse
Pulse Length	0.1ms to 1 s
Laser operation modes	Continuous Wave, Blend (PW), Super Pulse
Aiming beam	3mW (650nm diode) adjustable
Articulated arm	7-joint articulated arm
Cooling type	Closed loop (liquid)
User Interface	LCD Touch Screen
Power input requirements	110 - 120 VAC, 10 A, 50-60 Hz
Dimension (H x W x D)	150 x 46 x 31 cm

Performance Data:

None submitted.

Substantial Equivalence:

¹ The Er:YAG technical specifications of the Cortex Laser System are omitted as they remain unchanged and are not being compared to the predicate device.

The Cortex Laser System has the same intended uses and indications, technological characteristics, principles of operation as its predicate device. There are no new issues of safety or effectiveness. Thus, the Cortex Laser System is substantially equivalent to the predicate.