K073158

AUG 27 2008

Sculpture Er:YAG Laser System 510k Summary

HOYA ConBio
47733 Fremont Boulevard, Fremont, California 94538
510-445-4500 www.conbio.com 510-445-4550 Fax

Submitter:	HOYA ConBio, Inc. 47733 Fremont Blvd. Fremont, California 94538 Phone: 510-445-4500 Fax: 510-445-4550
Contact:	Mr. Jim Green Vice President of Engineering
Date Summary Prepared:	July 21, 2008
Device Trade Name:	DermaSCULPT Er:YAG Laser System
Common Name:	Dermatology Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX
Classification Code:	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.
Predicate (Equivalent) Device:	CB Erbium 2.94 (K970934) VersaWave Dental Laser System (K041710) Multilite Erbium:YAG Surgical Laser System (K933057) Fidelis XS (K990243) CuteraPearl (K070138) Mosaic Laser System (K070392) Erbium Fractional Handpiece (K071768) Profile Multi-Platform System (K070388) SmoothPeel (K unknown) Laser Peel.
Device Description:	The DermaSCULPT Er:YAG Laser System [DermaSCULPT] unit and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. The laser energy produced within the device is delivered to the tissue by means of Fiber Delivery System and specially designed

K073158

Scanner, Handpieces, Tips and Adaptors.

The user activates laser emission by means of a footswitch. The lamp power supply causes the flash lamp to light, causing the emission of an invisible infrared Er:YAG laser beam (2.94 microns). A visible white light pulsed beam from the flashlamp is used as an aiming beam. The laser beam passes through a partially reflecting mirror and then passes through the energy monitor, after which its power is measured. When all the pre-conditions have been satisfied and the READY button is pressed and the foot switch is depressed, the safety shutter opens and the laser beam is allowed into the delivery unit coupler.

The electrical system is comprised of the laser power supply, the control unit, calibrator, control panel, key switch, emergency stop switch, and foot switch. The components of the laser power supply include a high voltage power supply and a high voltage trigger control board. The high voltage power supply uses the high voltage to illuminate the flashlamp. The control unit comprises a microprocessor board, accessory board and other components that it controls. The calibrator measures the transmittance of the fiber delivery unit. The handheld scanner module is an attachment to the fiber.

Intended Use:

The DERMASCULPT is intended for Dermatological procedures requiring incision, excision, coagulation and vaporization of soft tissue. The specific indications using the applicable handpieces are as follows:

Skin resurfacing in the treatment of wrinkles and scar revision (including acne scars) with the non-fractionated handpiece.

Removal of cutaneous skin lesions with the micron tip handpieces including epidermal nevi, actinic chellitis, keloids, verrucae, skin tags, anal tags, keratosis, scar revision, (including acne scars), benign tumors and cysts, superficial skin lesions and diagnostic biopsies.

The DERMASCULPT with the fractionated scanner handpiece is intended/indicated for Dermatological procedures requiring coagulation of soft tissue and skin resurfacing.

Comparison:

Technical specifications, operating performance features, and general physical configuration: CB Erbium 2.94 (K970934), the VersaWave Dental Laser System (K041710) and the Multilite Erbium:YAG Surgical Laser System (K933057)

K073152

	Indications: Fidelis XS (K990243), Multilite Erbium:YAG Surgical Laser System (K933057), Cutera Pearl (K070138), Mosaic Laser System (K070392), Erbium Fractional Handpiece (K071768), Profile Multi-Platform System (K070388), CB Erbium/2.94 (K970934), SmoothPeel (K unknown) Laser Peel, Fraxel SR (K050841).
Nonclinical Performance Data:	The review of the technical characteristics, indications for use, mechanism of action, and verification and validation information provided demonstrate that the DermaSculpt is substantially equivalent to its predicate device.
Clinical Performance Data:	HOYA ConBio has established that the DermaSculpt performs as clinically intended and that no new issues of safety and effectiveness are introduced.
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hoya ConBio, Inc.
% Liza Burns and Associates
Ms. Liza Burns
Regulatory Consultant
19722 Westview Drive
Twain Harte, California 95383

AUG 27 2008

Re: K073158
Trade/Device Name: DermaSCULPT Er:YAG 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: II
Product Code: GEX
Dated: August 11, 2008
Received: August 25, 2008

Dear Ms. Burns:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K073158**

Device Name: **DermaSCULPT Er:YAG Laser System**

Intended Use/Indications for Use:

The DERMASCULPT is intended for Dermatological procedures requiring incision, excision, coagulation and vaporization of soft tissue. The specific indications using the applicable handpieces are as follows:

Skin resurfacing in the treatment of wrinkles and scar revision (including acne scars) with the non-fractionated handpiece.

Removal of cutaneous skin lesions with the micron tip handpieces including epidermal nevi, actinic chellitis, keloids, verrucae, skin tags, anal tags, keratosis, scar revision, (including acne scars), benign tumors and cysts, superficial skin lesions and diagnostic biopsies.

The DERMASCULPT with the fractionated scanner handpiece is intended/indicated for Dermatological procedures requiring coagulation of soft tissue and skin resurfacing.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073158