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5. 510(k) Summary or 510(k) Statement

Medlite C6 Q-Switched Nd: YAG Laser Medlite Compression Tool and Handpiece Attachment Accessories 510k Summary

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

K060977

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:	March 28, 2006
Device Trade Name:	Medlite™ Nd: YAG Laser System: Compression Tool and Handpiece Accessory
Common Name:	Dermatology Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Candela Pigmented Lesion Compression Handpiece Accessory – K051359 Medlite™ C6 Q-Switched Nd: YAG Laser / Standard MultiSpot™ Handpiece Accessory – K014234
Device Description:	The Compression Tool and Handpiece Attachment Accessories are intended to be used to assist and enhance the procedure of treating dermatological conditions The Compression Tool and Handpiece Attachment Accessories are additional accessories designed to accompany the currently offered MedLite MultiSpot Handpiece. The purpose for these accessories are purely for a cosmetic end to help reduce undesirable purpura while treating with the Medlite C Series lasers.
Intended Use:	For use in dermatology for all currently approved indications for the Medlite C-Series Nd: YAG Laser Systems and MultiSpot Handpiece.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2006

Hoya ConBio™
% Mr. Jim Green
Vice President of Engineering
47733 Fremont Boulevard
Fremont, California 94538

Re: K060977
Trade/Device Name: HOYA ConBio Compression Tool and Handpiece Accessories for use with MedLite™ C Series Q-Switched Nd: YAG Laser Systems
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: April 6, 2006
Received: April 10, 2006

Dear Mr. Green:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K060977

Device Name: HOYA ConBio Compression Tool and Handpiece Accessories for use with the MedLite™ C Series Q- Switched Nd: YAG Laser Systems.

Indications for Use: **Tattoo Removal**
Nevus of Ota
Hair Removal
Vascular Lesions
Dermal Pigmented Lesions
Epidermal Pigmented Lesions
Laser Resurfacing for Acne scars and wrinkles
Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

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)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

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(Posted November 13, 2003)

510(k) Number K060977