



APR - 7 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Dmitry Donskoy  
Product Manager  
DDC Technologies, Inc.  
2980 Waverly Avenue  
Oceanside, New York 11572

Re: K040055

Trade/Device Name: Polylase™ LP Dual Output Alexandrite and Nd:YAG Laser

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: November 14, 2003

Received: January 12, 2004

Dear Mr. Donskoy:

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.

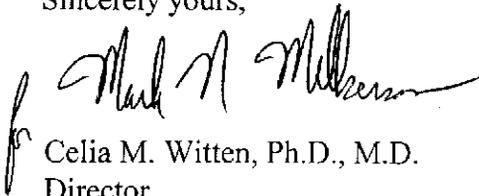
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 (301) 594-4659. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K040055

**INDICATIONS FOR USE STATEMENT**

510 (K) NUMBER: **K040055**

DEVICE NAME: **POLYLASE LP PULSED DUAL OUTPUT ALEXANDRITE AND Nd:YAG LASER**

INDICATIONS FOR USE:

1. The POLYLASE LP PULSED DUAL OUTPUT LASER is intended to effect TEMPORARY HAIR REDUCTION in skin types I-IV with 755 nm output wavelength) and skin types IV-VI with 1064 nm output wavelength.
2. The POLYLASE LP PULSED DUAL OUTPUT LASER is also intended to effect STABLE LONG-TERM, OR PERMANENT, HAIR REDUCTION in skin types I-III with use of 755 nm wavelength and skin types IV and V with use of 1064 nm wavelength through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.
3. FOR PHOTOCOAGULATION AND HEMOSTASIS OF DERMATOLOGICAL VASCULAR LESIONS with 1064 nm output wavelength.
4. FOR INCISION/EXCISION OF SOFT BODY TISSUES IN DERMATOLOGY with 1064 nm output wavelength.
5. FOR NONABLATIVE WRINKLE REDUCTION AND SKIN COLLAGEN REJUVENATION with 1064 nm output wavelength.

  
 (Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

K040055

(PLEASE DO NOT WRITE BELOW THIS LINE (DON'T INCLUDE ON ANOTHER PAGE IF NEEDED))

\_\_\_\_\_  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
 (Optional Format 1-2-96)