MAY 1 4 2004

K 040384

510(k) Summary of Safety and Effectiveness for the WaveLight Laser Technologie, AG MYDON C

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Contact Person:	Maureen O'Connell 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	April 28, 2004

2. **Names**

Device Name:	MYDON C
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. **Predicate Devices**

The MYDON C laser system is substantially equivalent to the Altus Medical CoolGlide Aesthetics Laser (K023954), the Laserscope Lyra Surgical Laser System (K020021), the Fotona DUALIS XP Plus Nd:YAG Laser System (K022839) and the Adept Medical Concepts 1064/532 Laser (K032220).

4. **Device Description**

The MYDON C is a 1064 nm solid-state long-pulsed Nd:YAG laser system. The beam is directed to the treatment area by a transmission system which is connected to the laser device and consists of a multifunction hose system and a tightly connected hand unit. In the multifunction hose system both laser radiation carrying quartz fiber as well as the cooling and signal leads are contained. The MYDON C transmission system includes skin cooling integrated into the hand unit and cools the area of skin that the laser covers. When the applicator is placed against the skin, its

shape and the integrated hand unit cooling system cool the treatment area before, during and after the application of the laser pulse, all in a single step.

The hand unit inserts allow for various treatment types and parameter ranges. MYDON C offers the 1.5 and 3 mm hand unit inserts specifically for the treatment of vascular lesions, the 5 mm hand unit insert for the treatment of both vascular lesions and wrinkles, the 7 mm and 10 mm hand unit inserts for hair removal.

5. Indications for Use

The MYDON C laser system is indicated:

1. For the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, and spider veins.
2. The MYDON C laser system is also indicated for the treatment of wrinkles.
3. The MYDON C is also indicated for the removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB).
4. The MYDON C laser system is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.
5. The intended use of the integral cooling system in the MYDON C laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2004

WaveLight Laser Technologie AG
c/o Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K040384
Trade/Device Name: MYDON C
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: February 13, 2004
Received: February 17, 2004

Dear Ms. O'Connell:

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 (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,

for Miriam C. Provost

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

510(k) Number (if known) K 040384

Device Name MYDON C

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K040384