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510(k) Summary of Safety and Effectiveness for the *Oculase MD*

K052354

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:	BIOLASE Technology, Inc. 4 Cromwell Irvine, CA 92618.
Contact Person:	Maureen O'Connell 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	June 30, 2006

2. **Names**

Device Name:	***Oculase MD***
Classification Name:	Ophthalmic Laser Product Code: HQF

3. **Predicate Devices**

The ***Oculase MD***® is substantially equivalent to a combination of the following devices: BIOLASE's WaterLase® (K031140, K030523, K012511, K011041), and DermaLase™ (K971459), MSq (M^2) Ltd. MSq Family of Lovely Light/Laser Systems (K042000), Laserscope's Erbium:YAG Laser System and Accessories (K971843), Aesculap-Meditec's MCL 29 Dermablate Erbium Laser System (K964128), Pfizer Laser Systems' Centauri (K905141), and the Friendly Light ER:YAG Pulsed Laser (K000023).

4. **Device Description**

The ***Oculase MD*** Er,Cr:YSGG (Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet) tissue cutting system is a unique device with diverse ophthalmic tissue applications. A flexible fiber optic with handpiece delivers the laser wavelength to the target tissue. A red light emitted from the handpiece distal end pinpoints the area of treatment. The optical power output may be adjusted to specific user requirements for tissue applications. Laser radiation is delivered

from the laser unit to the handpiece through the optical fiber. A sterile water spray is emitted at the same time laser radiation is delivered to the tissue site. The handpiece is rotatable and detachable from the optical shaft. The tip is detachable from the handpiece and serves as the optical power conduit to the target tissue.

5. **Indications for Use**

The ***Oculase MD*** is indicated for use in general ophthalmic soft tissue surgical indications such as: incision, excision, vaporization and coagulation of ocular tissue and tissue surrounding the eye and orbit.

6. **Performance Data**
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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BIOLASE Technology, Inc.
% Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K052354
Trade/Device Name: Oculase MD
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: June 7, 2006
Received: June 8, 2006

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 (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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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): K052354

Device Name: ***Oculase MD***

Indications for Use:

The ***Oculase MD*** may be indicated for general ophthalmic soft tissue surgical indications such as:

Incision, excision, vaporization and coagulation of ocular tissue and tissue surrounding the eye and orbit.

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)

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

510(k) Number K052354