K 032023

OCT - 1 2003

510(K) SUMMARY
W.O.M. Laser U100 Plus

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

Contact Person: Susanne Raab
320 North Columbus Street
Alexandria, VA 22314

Phone number: 703-299-0523

Date Prepared: June 25, 2003

Name of Device and Name/Adress of Sponsor:

W.O.M. Laser U100*plus*

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

Classification Name:

Laser instrument, surgical, powered

Common or Usual Name:

Intracorporal Laser Lithotripter in Urology and Gastroenterology

Predicate Device:

- W.O.M. Laser U100 (K023041)
- Dornier Medilas H/2 (K984591)

K032023

510(K) SUMMARY
Page -2- / -3-

Intended Use and Indication for Use:

- The W.O.M. Laser U100*plus* is intended for use in endoscopic surgical procedures to fragment stones.

- The W.O.M. Laser U100*plus* is indicated for use to fragment urinary stones (kidney, ureter and bladder) and biliary stones in the contact mode during closed surgical procedures.

Technical Characteristics and Substantial Equivalence:

The W.O.M. Laser U100*plus* and the predicate devices are intended for use in endoscopic surgical procedures to fragment stones. All three devices are indicated for use to fragment urinary and biliary stones in the contact mode during closed surgical procedures. However, the Dornier Medilas H/2 (K984591) is also indicated for use in cutting, vaporization, ablation and coagulation of soft tissue.

The W.O.M. Laser U100*plus* and the predicate device W.O.M. Laser U100 (K023041) have identical principles of operation and similar technological characteristics. Both devices use the same physical processes to generate the laser beams and method of transmission to the stone. The W.O.M. Laser U100*plus* and the predicate device transmit pulses of laser energy by a quartz fiber to the stone (contact mode). The laser pulses are transformed into an ultrasonic wave (acoustic impact waves) which mechanically crush the stone. The proposed device and the predicate device W.O.M. Laser U100 devices incorporate an internal water cooling cycle with a water-air heat exchanger system. In addition, both devices provide the same safety features and similar parameters are displayed on the operator panel of the devices. The differences between the two laser devices are a minor increasement of the pulse energy and pulse frequency and the option of a double pulse setting.

The W.O.M. Laser U100*plus* and the predicate device Dornier Medilas H/2 (K984591) generate their respective laser beam through different physical processes. The predicate device Dornier Medilas H/2 is a Holmium:YAG laser, that operates with a thermal decomposition of the stone material. Unlike the Dornier Medilas H/2, the laser effect of the W.O.M. Laser U100*plus* is non-thermal and does not lead to a critical heating of the operating area. This represents a substantial improvement in the safety of laser lithotripsy by avoiding the risk of tissue injury that may result from the use of an Holmimum:YAG laser to fragment stones in the urinary tract.

K032023

The differences of the W.O.M. Laser U100*plus* to the predicate device W.O.M. Laser U100 (K023041) are minor and raise no new questions of safety and effectiveness. Moreover the differences between both devices result in an improvement of the stone fragmentation efficiency. In addition, W.O.M. believes that the differences of the W.O.M. Laser U100*plus* and the Dornier Medilas H/2 (K984591) do not raise any concerns regarding the safety and effectiveness. Moreover, the non-thermal and non-cutting properties of the W.O.M. Laser U100*plus* represent a substantial improvement in the safety of laser lithotripsy.

Safety and Effectiveness Information:

In vitro, in vivo and clinical data has been provided to demonstrate that the W.O.M. Laser U100*plus* is safe and effective for the fragmentation of biliary stones in closed surgical procedures.

The device complies with the International Standard IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). In addition, the device meets the requirements of the Underwriter Laboratories Standard UL 2601-1 and bears the CE mark in accordance with the Medical Device Directive 93/42/EEC.

Conclusion:

The W.O.M. Laser U100*plus* has the same intended use, similiar design features and identical principles of operation as the predicate device W.O.M. Laser U100 (K023041). Moreover, the W.O.M. Laser U100*plus* has the same intended use and indication for use as the Dornier Medilas H/2 (K984591). The differences of the W.O.M. Laser U100*plus* to the predicate device W.O.M. Laser U100 (K023041) are minor and raise no new questions of safety and effectiveness. Finally, in vitro, in vivo and clinical study results demonstrate that the W.O.M. Laser U100*plus* is safe and effective for the fragmentation of urinary and biliary stones in closed surgical procedures.

Accordingly, W.O.M. WORLD OF MEDICINE AG believes that the W.O.M. Laser U100*plus* is substantially equivalent to the W.O.M. Laser U100 (K023041) and the Dornier Medilas H/2 (K984591).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2003

W.O.M. World of Medicine AG
c/o Ms. Susanne Raab
320 North Columbus Street
Alexandria, Virginia 22314

Re: K032023
Trade/Device Name: W.O.M. Laser U100*plus*
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 25, 2003
Received: July 17, 2003

Dear Ms. Raab:

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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K032023

Device Name: W.O.M. Laser U100*plus*

Indications for Use:

The W.O.M. Laser U100*plus* is indicated for use in the contact mode to fragment urinary stones (kidney, ureter and bladder) and biliary stones in closed surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescripition Use ✓ OR Over-The-Counter Use_____ (Per 21 C.F.R. 801.109)

Miriam C. Provost (Optional Format 3-10-98)

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

510(k) Number K032023