JAN 2 7 2003

510(K) Summary of Safety and Effectiveness

Applicant : TERABYTE Company K 022341

Address : 5480 Hirakuchi, Hamakita-city, Shizuoka-Prefecture, 434-0041 Japan

Contact : Dr. William A. Olson, U.S Authorized Agent

Telephone : 703 590 7337

Preparation Date :

Device Trade Name : TERABYTE 2000 Hair Remover

Common Name : Laser Instrument for hair removal

Classification Name :
Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see 21 CFR 878.4810)
Product code : GEX
Panel : 79.

Legally-marketed Predicate Devices :
Coherent Inc., Light Sheer Family
(Light Sheer SP, Light Sheer EP, Light Sheer SC, and Light Sheer EC)
Cynosure Corp., Apogee 6200, and Apogee 9300

System Description :
TERABYTE 2000 Hair Remover delivers pulsed infrared laser light at a wavelength of 810 nm with selectable pulse duration of 5 – 50 ms, and a selectable fluence of 10 –65 J/cm^2. The laser pulses are capable of generating a maximum pulse repetition frequency of 1 Hz by several arrays of diode lasers located in the handpiece.

The complete system consists of a console and handpiece connected to the system by an umbilical. In standard use, the handpiece is pressed against the patient's skin and a pulse of light is delivered. To initiate energy output the system requires the set up of

the touch-screen , and concurrent activation of three of the following : the handpiece skin touch switch, handpiece trigger , and footswitch. The cryogen is splayed from the top of the handpiece to provide active skin cooling. Laser parameters and other system features are controlled from the touch-screen on top of the console, which provides an interface to the system computer.

Intended Use of the Device :

TERABYTE 2000 System is intended for hair removal and permanent hair reduction. The TERABYTE 2000 System is intended for use on all skin types (Fitzpatrick Skin Types) , including tan skin. The device is intended for prescription use.

Performance Data :

None.

The specifications and indications for use of the TERABYTE 2000 System are the same or very similar to those of the claimed predicate devices. The TERABYTE 2000 System has the same or very similar indications for use for which the claimed predicates have been cleared. Because of this, performance data were not required.

Conclusion:

Based on the foregoing, the TERABYTE 2000 System is substantially equivalent to the legally-marketed claimed predicate device for the purpose of this 510(K) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 7 2003

Terabyte Company
William A. Olson
c/o Center for Regulatory Services, Inc.
5200 Wolf Run Shoals Road
Woodbridge, Virginia 22192

Re: K022341
Trade/Device Name: Terabyte 2000 Hair Remover
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic Surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 28, 2002
Received: October 29, 2002

Dear Mr. Olson:

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). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for 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: K022341

DEVICE NAME: TERABYTE 2000 Hair Remover

INDICATIONS FOR USE:

TERABYTE 2000 System is intended for hair removal and permanent hair reduction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K022341