

K970461

JUL 11 1997

Attachment I
510(K) Summary
Cell Robotics Er:YAG Pulsed Surgical Laser System

This 510(K) Summary of safety and effectiveness for the Cell Robotics Er:YAG Surgical Laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: Cell Robotics, Inc.

Address: 2715 Broadbent Parkway NE,
Albuquerque, NM 87107

Contact Person: Connie White, Manager of Regulatory Affairs

Telephone: (505) 343-1131 Ext. 108
(505) 344-8112

Preparation Date: 1-31-97

Device Trade Name: Cell Robotics Er:YAG Surgical Laser (to be determined)

Common Name: Er: YAG Pulsed Surgical Laser

Classification Name: Instrument, Surgical, Powered, laser
79-GEX
21 CFR 878-48

Legally Marketed Predicate Device: Schwartz Electro-Optics TriLase2940
510(K) # K 954013

Description of the Cell Robotics Er:YAG Surgical Laser: The Cell Robotics Er:YAG Surgical Laser is an Er:YAG laser producing laser emission at 2940nm. The laser consists of three interconnected sections: The cabinet which houses the power supply, the cooling system and the microcontroller, the swing arm and the handpiece, which houses the laser.

Intended use of the Cell Robotics Er:YAG Surgical Laser: The Cell Robotics, Inc. unnamed Er:YAG Surgical laser is indicated for use in small and large joint Arthroscopy, including microdissectomies, endoscopic procedures and general surgical procedures for cutting (incision / excision), vaporizing and coagulation of soft tissues, including skin, subcutaneous tissue, muscle, meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The Cell Robotics Er:YAG Surgical Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for dermatology treatments such as skin resurfacing and dermabrasion

Additional Information: None requested at this time



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Connie White
Cell Robotics, Inc.
2715 Broadbent Parkway, NE
Albuquerque, New Mexico 87107

JUL 11 1997

Re: K970461
Cell Robotics Er:YAG Surgical Laser
Regulatory Class: II
Product Code: GEX
Dated: May 21, 1997
Received: May 28, 1997

Dear Ms. White:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

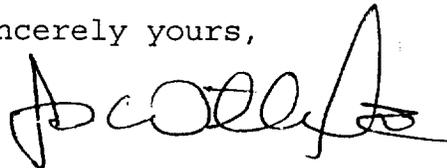
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: 970461

Device Name: Cell Robotics Er:YAG Surgical Laser

Indications for Use:

The Cell Robotics, Inc. unnamed Er:YAG Surgical laser is indicated for use in small and large joint Arthroscopy, including microdiscectomies, endoscopic procedures and general surgical procedures for cutting (incision / excision), vaporizing and coagulation of soft tissues, including skin, subcutaneous tissue, muscle, meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 970461

Prescription Use
(per 21 CFR 801.109)

OR

Over-the-Counter Use