DEC 2 2 2003

K 033799

510(K) Summary
Cell Robotics' Clinical Lasette P-200 Laser Skin Perforator

This 510(K) Summary of safety and effectiveness for the Cell Robotic's Clinical Lasette P-200 Laser Skin Perforator 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:	Linda A. Blair, Assistant Quality Manager
Telephone:	(505) 343-1131 Ext. 124 (505) 344-8112
Preparation Date:	12-3-03
Device Trade Name:	Clinical Lasette P-200
Common Name:	Laser skin perforator
Classification:	Class II
Legally Marketed Predicate Device:	Cell Robotics, Inc. Lasette Plus
Description of the Cell Robotic's Lasette Laser Skin Perforator	The Cell Robotics Lasette laser skin perforator is a portable battery operated laser device. The device produces a single pulse of laser light which ablates a small hole in the patient's fingertip comparable to that produced by commonly used stainless steel blood lancets.
Intended use	Ablation of skin for collecting capillary blood samples for subsequent analysis.
Indications for use	The Cell Robotic's Lasette Laser Skin Perforator is indicated for use by qualified healthcare professionals for the perforation of skin to draw capillary blood for screening purposes.
Contraindications for Use	The Lasette should not be used to collect samples for use in analyzers that require complex sample transfer procedures.

Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The Cell Robotic's Clinical Lasette P-200 Laser Skin Perforator is substantially equivalent to the predicate device.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2003

Ms. Linda A. Blair
Assistant Quality Manager
Cell Robotics, Inc.
2715 Broadbent Parkway NE, Suite A-E
Albuquerque, New Mexico 87107

Re: K033799
Trade/Device Name: Clinical Lasette P-200
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: December 3, 2003
Received: December 5, 2003

Dear Ms. Blair:

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,

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: K 033799

Device Name: Lasette Laser Skin Perforator
Trade Name: Clinical Lasette P-200

Indications for Use:

The Cell Robotic's Clinical Lasette P-200 Laser Skin Perforator is indicated for use by qualified healthcare professionals for the perforation of skin to draw capillary blood for screening purposes.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ision Sign-Off)
...ision of G... Restorative
... Neurological Devices
...K033799

Prescription Use ✓ OR Over-the-Counter Use____
(per 21 CFR 801.109)