K973431

OCT 28 1997

Appendix B
510(K) Summary
Cell Robotic's Lasette Laser Skin Perforator

This 510(K) Summary of safety and effectiveness for the Cell Robotic's Lasette 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:	Connie White, Manager of Regulatory Affairs
Telephone:	(505) 343-1131 Ext. 108 (505) 344-8112
Preparation Date:	9 4 97
Device Trade Name:	Cell Robotics' Lasette
Common Name:	Laser skin perforator
Classification:	Class II
Legally Marketed Predicate Device:	Glucolet Steel Lancet Mfg. By Bayer Diagnostics Feather Touch Steel Lancet Mfg. by Ulster Scientific Tenderlett Steel lances Mfg. By International Technidyne TriLase 2940 Mfg. by Schwartz Electro-Optics Medlite Mfg. by Continuum Biomedical Protégé Mfg. By Xintec Corp.
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 of the Cell Robotic's Lasette Laser Skin Perforator	Ablation of skin tissue to establish capillary blood access.
Indications for use	The Cell Robotics Lasette Laser Skin Perforator is intended for use by qualified healthcare professionals for collecting capillary blood samples from adult patients, for subsequent determination of blood glucose concentration and hematocrit using optically based measurement techniques.
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:	The subject device has been investigated in two human clinical trials under approved Investigational Device Exemptions. Results from the clinical trials indicate that the device is safe and effective.
Conclusion:	The Cell Robotic's Lasette Laser Skin Perforator is substantially equivalent to the predicate devices.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

OCT 28 1997

Re: K973431
Trade Name: Cell Robotics Lasette
Regulatory Class: II
Product Code: GEX
Dated: September 5, 1997
Received: September 10, 1997

Dear Ms.White:

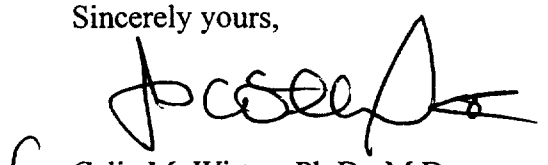
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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 requirements , 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,



for 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: K973431

Device Name: Lasette laser skin perforator

Indications for Use:

The Cell Robotics Lasette Laser Skin Perforator is intended for use by qualified healthcare professionals for collecting capillary blood samples from adult patients, for subsequent determination of blood glucose concentration and hematocrit using optically based measurement techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973431

Prescription Use X
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)