

AUG 14 1997

K965124



CELL
ROBOTICS
INC.

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Contact Ms. Connie White
Regulatory Affairs Officer

**CELL ROBOTICS' LASETTE™ LASER SKIN PERFORATOR
510(k) SUMMARY**

- 1. Date of Preparation: August 13, 1997(Rev. 3)
- 2. Device Name:
 - 1. Common Name: Laser Skin Perforator
 - 2. Tradename: Lasette
- 3. Intended Use: The Cell Robotics Lasette is intended for use for skin perforation and establishing capillary blood access for blood sampling.
- 4. Indications for Use: The Cell Robotics Lasette is indicated for use by qualified healthcare workers for perforation of the skin to draw capillary blood from healthy adult patients for subsequent determination of blood glucose concentration and hematocrit using colorimetric measurements.
- 6. FDA Device Classification: Not classified under 21 CFR 862-892 or listed in CDRH publication #95-4246. Applicant suggests Class II.
- 10. Applicant's FDA Registration Number: (not yet received)
- 11. Brief Product Description: 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 a patient's fingertip comparable to that produced by commonly used stainless steel blood lancets. The complete Lasette product includes the Lasette, its labeling and manual, and single-use sanitary (non-sterile) plastic lens shields. The Lasette uses a small convection-cooled erbium:YAG solid state laser with a maximum output energy of 0.5 J per pulse at a wavelength of 2.94 micrometers and a pulse width of 300 microseconds. This energy is focused on a target spot with a diameter of 300 micrometers.

12. Performance Standards: The laser aspects of the Lasette are consistent with classification as a Class IV medical laser product and the device has been designed to comply with performance standard regulations under 21 CFR 1040.10 and 1040.11.

13. Substantial Equivalence: The Lasette is substantially equivalent, with regard to aspects of therapeutic function and effect, to commercially available blood lancet devices. The Lasette is substantially equivalent, with regard to aspects of its technological characteristics, to commercially available solid state laser devices for dermatological surgery.

14. Performance Data: The subject device has been investigated in a human clinical trial directed toward determining the effect of use upon reliability of analytical results. The study data supports a conclusion that results of glucose and hematocrit determinations are not significantly affected by use of the device. Certain in vitro testing has been done to establish reliability of output energy calibration and depth of penetration. These tests support a conclusion that the device energy indicator represents the output energy to within 20% of the indicated value and that penetration depth is approximately half of the depth predicted by the equation $d=H/F$, where d is wound depth H is the heat of ablation for water in Joules per unit volume, and F is the energy fluence projected by the device onto the skin.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 14 1997

Re: K965124
Trade Name: Lasette Laser Skin Perforator
Regulatory Class: II
Product Code: GEX
Dated: May 15, 1997
Received: May 16, 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.

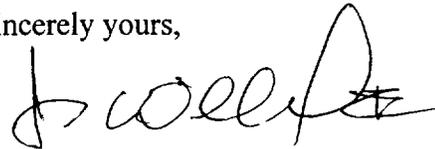
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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: K965124

Device Name: Lasette laser skin perforator

Indications for Use:

The Cell Robotics Lasette is indicated for use by qualified healthcare workers for perforation of the skin to draw capillary blood from healthy adult patients for subsequent determination of blood glucose concentration and hematocrit using colorimetric measurements.

(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

K965124

Prescription Use X
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)