K981063

JUN 23 1998

510(k) Summary

SUBMITTED:

Submitted on behalf of:

Company Name:	Laser Center Development Corporation
Address:	709 The Hamptons Lane Town & Country, MO 63017
Phone:	314-514-1478
Fax:	314-434-7030

CONTACT PERSON: Francis E. O'Donnell, Jr., M.D.

OFFICIAL CORRESPONDENT: Francis E. O'Donnell, Jr., M.D.

Firm Name:	Laser Center Development Corporation
Address:	709 The Hamptons Lane Town & Country, MO 63017
Phone:	314-514-1478
Fax:	314-434-7030

DATE SUMMARY PREPARED: June 2, 1998

TRADE NAME: Automated Corneal Trephine

COMMON NAME: Corneal Trephine

SUBSTANTIALLY EQUIVALENT TO: The Automated Corneal Trephine, by Laser Center Development Corporation, is substantially equivalent to the Barron-Hessburg manual corneal trephine (K864520).

DESCRIPTION OF THE DEVICE: The Automated Corneal Trephine consists of a sterile, single use, disposable corneal trephine made of medical grade injection-molded plastic and stainless steel. The trephine is used to create a partial or full-thickness circular cut for lamellar or penetrating keratoplasty. This trephine features a DC motor which automatically rotates the trephine, eliminating cumbersome manual rotation. The blade depth is preset at the factory so that the extent of penetration is very precise.

INDICATIONS FOR USE: The Automated Corneal Trephine is intended for preparation of recipient and donor corneas for lamellar and penetrating keratoplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1998

Francis E. O'Donnell, Jr., M.D.
President
Laser Center Development Corporation
1028 South Kirkwood Road, Suite A
St. Louis, MO 63122

Re: K981063
Trade Name: Automated Corneal Trephine
Regulatory Class: I
Product Code: 86 HRG
Dated: June 2, 1998
Received: June 2, 1998

Dear Dr. O'Donnell:

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) 594-4613. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981063

Device Name: Automated Corneal Trephine

Indications For Use:

- Lamellar keratoplasty
- Penetrating Keratoplasty

(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 Ophthalmic Devices
510(k) Number K981063

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)