JUL 15 1998

**K981235**
**Oculostat**

**510(k) Summary**

**SUBMITTED:**

**Submitted on behalf of:**


| | |
|---|---|
| Company Name: | Laser Center Development Corporation |
| Address: | 709 The Hamptons Lane<br>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.

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|---|---|
| Firm Name: | Laser Center Development Corporation |
| Address: | 709 The Hamptons Lane<br>Town & Country, MO 63017 |
| Phone: | 314-514-1478 |
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**DATE SUMMARY PREPARED:** May 27, 1998

**TRADE NAME:** Oculostat

**COMMON NAME:** Ophthalmic speculum

**SUBSTANTIALLY EQUIVALENT TO:** The Oculostat™ by Laser Center Development Corporation is substantially equivalent to the Eye Fixation Speculum, by eyeFix, Inc., which was determined by FDA to be marketable per K964289.

**DESCRIPTION OF THE DEVICE:** The Oculostat by Laser Center Development Corporation consists of a scleral vacuum suction ring attached to a medical quality plastic ophthalmic speculum. After retracting the eyelids and inserting the lid margins into the speculum portion of the Oculostat, the suction-vacuum ring is attached to the sclera by sequentially centering, depressing, and engaging low vacuum (30mm Hg or less) by pump or spring-loaded syringe. The frictional forces between the eyelids and speculum, together with the vacuum ring, hold the eye steady despite extraocular muscle activity.

**INDICATIONS FOR USE:** The Oculostat, by Laser Center Development Corporation, is intended to reduce eye movement and stabilize the eye in any procedure in which the globe needs to be immobilized. The device is provided sterile and it is disposable for single use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1998

Francis E. O'Donnell, Jr., M.D.
President
Laser Center Development Corp.
1028 S. Kirkwood Road, Suite A
Kirkwood, MO 63122-7222

Re: K981235
Trade Name: Oculostat Speculum
Regulatory Class: I
Product Code: 86 HNC
Dated: May 27, 1998
Received: May 29, 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, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981235

Device Name: Oculostat

Indications For Use:

Oculostat is intended to reduce eye movement and stabilize the eye in any procedure in which the globe needs to be immobilized.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

A M Williams

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981235