JUL 13 1999

K990872

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

01. DEVICE NAME (Trade, common, and classification): Scleral Plug.

02. PREDICATE DEVICE(s): K854507, et al, submissions, information attached, which were determined to be SE.

03. DESCRIPTION: Scleral plugs, 19 and 20 ga., for use in ophthalmic surgical procedures. Both as stainless steel, with the 19 ga. plugs gold plated, and the 20 ga. plugs silver plated.

04. INTENDED USE: To provide single-use scleral plugs, to maintain patency of a previously made incision in the sclera of the eye, during ophthalmic surgical procedures performed by a certified clinician in a clinical setting.

05. We believe this submission should be found substantially equivalent by virtue of the following points, expanded upon elsewhere in this submission:

5.1. No substantitive change in materials, basic components, or method of manufacture between this device and the predicate(s); the raw materials/components used have been used in the medical industry on similiar/identical products and for similiar/ identical uses since pre-amendment, without any record of patient problems or adverse reactions;

5.2. No change in basic configuration or construction;

5.3. These devices and their components have been tested by an independent lab for biocompatability (cyctotoxicity, hemolysis), and will be subjected to inspection/ testing at IQC, and during/after manufacture and prior to release to the field.

5.4. The function and use of this product will be no different than that of the predicate devices, and countless other similiar devices in the marketplace since pre-amendment.

06. There are no substantive differences between the products defined in this 510(k) submission and the predicate devices.

Prepared 03/09/99
Ammended 04/19/99

Signed: Timothy H Barker Dated: 3/11/99

Timothy Barker, President/CEO, Director of Sales/Marketing
OPHTHALMIC CONSULTANTS, INC.
P O Box 2728
11232 120th Avenue Northeast, Suite 109
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 1999

Ophthalmic Consultants, Inc.
c/o Mr. John E. Lincoln
J. E. Lincoln and Associates
65 N. Main
Suite 101
P.O. Box 154
Tooele, UT 84074

Re: K990872
Trade Name: Scleral Plugs, 19 and 20 Gauge
Regulatory Class: II
Product Code: 86 LXP
Dated: March 11, 1999
Received: March 16, 1999

Dear Mr. Lincoln:

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):_____

Device Name: SCLERAL PLUG

Indications For Use:

The scleral plugs are provided as part of single- and multiple-use surgical component kits/packs, or as kit replacements, in order to maintain patency of a previously made incision in the sclera of the eye, during ophthalmic surgical procedures, performed by a certified clinician in a clinical setting.

(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 K990872

Prescription Use XX OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)