NOV - 4 1997

K973220

Section 9
510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

1. The submitter of this premarket notification is:

David Link, Executive Vice-President
EXPERTech Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742-5307
Tel.: (508) 371 - 0066
Fax : (508) 371 - 1676

This summary was prepared on August 21, 1997.

2. The names of these devices are the Rodenstock RO 5000 AR, the RO 5000 FDY, and the RO 5000 AR/FDY. The common name is laser slitlamp, and its classification name is AC-powered slitlamp biomicroscope (with laser adapter).

3. The above models of the Rodenstock RO 5000 slitlamp, modified for laser system delivery, are substantially equivalent to the Zeiss SL 130 laser slitlamp fitted with the Zeiss Visulink Diode for use with the Zeiss Visulas Diode II argon laser that is manufactured by Carl Zeiss, Inc.

4. The above models of the modified Rodenstock RO 5000 are slitlamp instruments fitted with a laser adapters, and motor activated, metal-coated safety filters. When used with a laser, the laser beam and the beam path of the slit projection are coupled coaxially via beam splitter cubes. This results in the laser focus and the slit image being projected in a common plane. The beam splitter is operated by a micromanipulator, and can be adjusted in any desired direction by pneumatically driven elements.

5. The devices are intended primarily for diagnostic ophthalmologic examinations, and as a laser delivery system for treatment of patients with eye disorders. When interfaced with a laser, the device can be used in therapeutic applications to perform retinal coagulation.

The indications are for retinal treatment only, and therefore, are within, but not as broad as those claimed by the predicate device.

6. The technological characteristics are the same or similar to those found with the predicate device where the eye is either examined by slitlamp, or treated by using the laser adapted slitlamp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

G. Rodenstock Instrumente GmbH
c/o Mr. David Link
EXPERTech™ Associates, Inc.
100 Main Street, Suite 120
Concord, Massachusetts 01742

NOV - 4 1997

Re: K973220
Trade Name: Rodenstock RO 5000 AR, RO 5000 FDY, and RO 5000 AR/FDY Laser Slitlamps
Regulatory Class: II
Product Code: HQF
Dated: August 25, 1997
Received: August 27, 1997

Dear Mr. Link:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

510(k) Number (if known): K973220

Device Name: Rodenstock RO 5000 AR, RO 5000 FDY, RO 5000 AR/FDY Laser Slitlamp

Indications For Use:

The Rodenstock RO 5000 AR, RO 5000 FDY, and RO 5000 AR/FDY Laser Slitlamps are indicated for diagnostic opthalmologic examination of patients with eye disorders. When interfaced with a laser, the device is used for therapeutic treatment of patients where retinal coagulation is indicated.

The following prescription legend will appear on the labeling for products distributed in the United States:

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

(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 K973220

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

06

(Optional Format 1-2-96)