K973757

510(k) Summary
Dutch Ophthalmic, USA
D.O.R.C. SOLUX Light Source
(per 21 CFR 807.92)

NOV - 7 1997

SUBMITTER NAME AND ADDRESS

Dutch Ophthalmic, USA
One Little River Road
P.O. Box 968
Kingston, NH 03848

Contact Person: Mark W. Furlong, President
Telephone: 603-642-8468

Date Prepared: October 1, 1997
Date Amended: November 3, 1997

DEVICE NAME

Proprietary Name:	SOLUX Light Source
Common/Usual Name:	Endoillumination System
Classification Name:	Ophthalmic Light Source

PREDICATE DEVICE/S

Grieshaber Light Source
Escalon VitLite I (K963417)

DEVICE DESCRIPTION

The D.O.R.C. SOLUX Light Source uses a halogen lamp and an internal focusing system to focus the light into the end of the optical fiber. Accessories to the Illumination Unit include adapters and color filters.

INTENDED USE

The D.O.R.C. SOLUX Light Source is indicated for intraocular illumination in vitreoretinal surgery.

BASIS FOR SUBSTANTIAL EQUIVALENCE

Operational and technological characteristics form the basis for the determination of substantial equivalence of the D.O.R.C. SOLUX Light Source with legally marketed predicate devices. Information supplied in this premarket notification includes descriptive information about the intended use, operation and technological characteristics. The following table summarizes the technological characteristics of the D.O.R.C. SOLUX Light Source in comparison to the predicate devices.

Comparison of SOLUX Light Source to Predicate Devices

Characteristic		SOLUX Light Source	Grieshaber Light Source	Escalon VitLite
Indication: Endoillumination for vitreoretinal surgery		YES	YES	YES
Lamp Type		Halogen	Halogen	Metal Halide
Lamp Rating		100 watts	not specified	not specified
Light Output (lumens)		High: 3800 Low: 3200	not specified	not specified
Color Temperature (degrees K)		High: 3220 Low: 3160	not specified	5300
Variable Intensity		Yes	Yes	Yes
Wavelength Range (nm)		400-800	not specified	450-700
UV filtration		Yes	Yes	Yes
Additional color filtration	Green	Yes	Yes	not specified
	Yellow	Yes	Yes	not specified
	Red	Yes	Yes	not specified
	Blue	Yes	Yes	not specified
	Daylight	Yes	Yes	not specified
Adapts to multiple accessories		Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 1997

Mr. Mark W. Furlong
President
Dutch Opthalmic, USA
One Little River Road
P.O. Box 968
Kingston, NH 03848

Re: K973757
Trade Name: D.O.R.C. Solux Light Source
Regulatory Class: II
Product Code: 86 MPA
Dated: September 29, 1997
Received: October 2, 1997

Dear Mr. Furlong:

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): K973757

Device Name: D.O.R.C. SOLUX Light Source

Indications For Use:

The D.O.R.C. SOLUX Light Source is indicated for intraocular illumination in vitreoretinal surgery.

Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973757

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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