3/3/99

K983797

510(k) Summary
Dutch Ophthalmic, USA
D.O.R.C. Harmony Total
(per 21 CFR 807.92)

1. 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 26, 1998

2. DEVICE NAME

Proprietary Name:	D.O.R.C. Harmony Total Vitrectomy System
Common/Usual Name:	Vitrectomy System
Classification Name:	Vitreous Aspiration & Cutting Instrument (86HQE & 21CFR 886.4150)

3. PREDICATE DEVICE/S

Manufacturer	Product Name	510(k) Number
Alcon Surgical	Accurus	unknown
Storz	Millenium	K961310
MID Labs	SupraVit/VitMate	K932669/K924222
Scieran	Vit Commander	K961738

4. DEVICE DESCRIPTION

The D.O.R.C. Harmony Total Vitrectomy System is an integrated system for posterior segment eye surgery. It provides the majority of functions required by the ophthalmic

surgeon for performing a vitrectomy including vitreous cutting and aspiration, phacofragmentation, illumination, diathermy, air system and viscous fluid injection/extraction. The system is operated from one multifunction footswitch which gives the surgeon control over all of the surgical functions.

The D.O.R.C. Harmony Total Vitrectomy System which includes the system, multifunction footswitch, trolley, automatic infusion pole and various sterile and non-sterile accessories provides the majority of functions needed to complete a posterior segment vitrectomy. The system is ac powered and also requires a source of medical grade compressed air to provide for some of the system functions.

5. INTENDED USE

The D.O.R.C. Harmony Total Vitrectomy System is a surgical system for ophthalmic surgery intended for use in surgery of the posterior segment (vitrectomy).

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Operational and technological characteristics form the basis for the determination of substantial equivalence of the D.O.R.C. Harmony Total 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. Harmony Total in comparison to the predicate devices.

	D.O.R.C. Harmony Total	Alcon Surgical Accurus	Storz Millenium	MID Labs SupraVit/VitMate Vitreoretinal System	Scieran Technologies Vit Commander
510(k) number	current submission	unknown	K961310	K932669/K24222	K961738
Intended Use	Posterior segment ophthalmic surgery	Posterior segment ophthalmic surgery	Posterior segment ophthalmic surgery	Posterior segment ophthalmic surgery	Posterior segment ophthalmic surgery
Features/Specifications					
Computer Based System	NO	YES	YES	unknown	unknown
Vitrectomy	YES	YES	YES	YES	YES
type:	guillotine cutter	guillotine or radial reciprocating cutter	guillotine cutter	guillotine cutter	guillotine cutter
drive mechanism:	pneumatic or electric	pneumatic	pneumatic	pneumatic	electric
maximum cut rate:	800 cuts/minute	800 or 1200 cuts/minute	750 cuts/minute	800 cuts/minute	2500 cuts/minute
Irrigation/Aspiration	YES	YES	YES	YES	YES
aspiration type:	venturi	venturi	venturi	unknown	unknown
linear control:	YES	YES	YES	YES	YES
maximum vacuum:	500 mm Hg	600 mm Hg	550 mm Hg	500 mm Hg	600 mm Hg
Phacofragmentation	YES	YES	YES	YES	NO
frequency:	40 kHz	40 kHz	28.5 khz	40 khz	
Diathermy	YES	YES	YES	YES	YES
frequency:	13.56 MHz	unknown	unknown	600 khz	unknown
maximum power:	12 watts	unknown	7.5 watts	10 watts	unknown
Fiber Optic Light Source	YES	YES	YES	YES	NO
dual/single output:	dual	dual	dual	dual	
lamp type:	halogen	unknown	unknown	unknown	
lamp wattage:	150 watts	unknown	unknown	unknown	
Air Infusion	YES	YES	YES	YES	NO
maximum pressure:	95 mm Hg	120 mm Hg	100 mm Hg	99 mm Hg	
Viscous Fluid Injection	YES	YES	NO	NO	NO
viscosities:	1000 or 5000 cs	1000 or 5000 cs			
Viscous Fluid Extraction	YES	YES	NO	NO	NO
Multifunction Footswitch	YES	YES	YES	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1999

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

Re: K983797
Trade Name: D.O.R.C. Harmony Total Vitrectomy System
Regulatory Class: II
Product Code: HQE
Dated: February 17, 1999
Received: February 24, 1999

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): K983797

Device Name: D.O.R.C. Harmony Total

Indications For Use:

The D.O.R.C. Harmony Total vitrectomy system is a surgical system for ophthalmic surgery intended for use in surgery of the posterior segment (vitrectomy).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Everette J Beem

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983797

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