K031404

MAY 22 2003

Premarket Notification, 510(k) Summary

Date: 5/2/03

Submitter Information:
Jeff B. Paul
Director, Quality Assurance and Regulatory Affairs
Phacor Inc., A Santen Company
775 Fiero Lane
San Luis Obispo, CA 93401
805-546-1815
805-546-1826 fax

Device Name:

Trade or Proprietary Name:	Dignity™ Ophthalmic Surgical System
Common or Usual Name:	Phacofragmentation unit
Classification Number:	21 CFR section 886.4670

Predicate Device Comparison:

The Dignity™ Ophthalmic Surgical System device that is the subject of this 510(k) is substantially equivalent to predicate devices marketed by Advanced Medical Optics Inc., Alcon Laboratories Inc. and Bausch & Lomb. The Advanced Medical Optics device most closely equivalent to the Phacor Inc. device is the Sovereign™, cleared for commercial distribution under 510(k) number K981116. The Alcon Laboratories device most closely equivalent to the Phacor Inc. device is the Legacy® Series 20000™, cleared for commercial distribution under 510(k) number K955789. The Bausch & Lomb device most closely equivalent to the Phacor Inc. device is the Millenium™, cleared for commercial distribution under 510(k) number K980488.

The significant differences between the Dignity™ Ophthalmic Surgical System and the three predicate devices, Sovereign™, Legacy™ and Millenium™ are listed below:

- External and internal structural differences. The external differences are in size, weight, and configuration. Also the Graphical User Interface has a different navigational format.
- Software will facilitate a more user friendly format in coordination with the footpedal and cassette/cartridge loading and unloading.

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Device Description:

The Dignity™ Ophthalmic Surgical System is used by ophthalmic surgeons to perform cataract surgery. The system utilizes accessories connected to the console to perform the cataract surgery.

Intended Use:

The Dignity™ Ophthalmic Surgical System is a Phacofragmentation device intended for use in cataract surgery to emulsify, and extract the cataract.

Summary of non-clinical tests:

Performance tests were conducted on the Dignity™ Ophthalmic Surgical System. The performance in an *in vitro* model was substantially equivalent to the predicate devices with respect to Phacoemulsification, Irrigation/Aspiration, Diathermy and Vitrectomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2003

Phacor Inc., A Santen Company
c/o Jeff B. Paul
Director, Quality Assurance & Regulatory Affairs
775 Fiero Lane
San Luis Obispo, CA 93401

Re: K031404
Trade/Device Name: Dignity™ Ophthalmic Surgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: May 2, 2003
Received: May 8, 2003

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031404

Device Name: Dignity™ Ophthalmic Surgical System

Indications for Use:

The Dignity™ Ophthalmic Surgical System is a Phacofragmentation device intended for use in cataract surgery to emulsify, and extract the cataract.

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

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)

Denis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031404