K981116

O. Premarket Notification [510(k)] Summary

This summary document is being submitted in accordance with section 807.92(c).

The submitter of the 510(k) is:

Marcia S. Yaross, Ph.D.
Director, Worldwide Regulatory Affairs and Medical Compliance
Allergan, Inc.
2525 Dupont Ave.
Irvine, CA 92713-9534
714-246-2362 phone
714 246-2205 fax

Date Summary Prepared: March 26, 1998

Device Subject to this 510(k):

Trade Name:	Sovereign™ Cataract Extraction System
Common Name:	Phacofragmentation or Phacoemulsification System
Classification Name:	Phacofragmentation System (886.4670)

Comparison with Predicate Devices:

The device which is the subject of this 510(k), Sovereign™ Cataract Extraction System, is substantially equivalent to the other AMO® cataract extraction devices which were authorized for marketing via 510(k) K971186 (AMO®Diplomax® System-modified), K946054 (AMO®Diplomax® System), and K924235 (AMO®Prestige® system). The handpiece component of the Sovereign™ system is equivalent to ultrasonic handpieces authorized for marketing under 510(k) K951462 (AMO®ProFicient® Handpiece), and K844373 (AMO®Series III® Handpiece). The manufacturer of the predicate devices is Allergan.

The significant changes to the predicate devices are:

1. The name is changed to the Sovereign™ Cataract Extraction System.
2. There is structural redesign, both internally and to the user interface.
3. There are changes in the system control architecture.
4. A new pressure measurement system, similar to that of the AMO®Prestige®, is employed.
5. There is new host software and redesigned printed circuit boards.
6. A new biocompatible material is used in the OPO55 reusable tubing sets.
7. A new graphical user interface (LCD display) is introduced.
8. The phaco handpiece has been redesigned.

K981116

Device Description:

The Sovereign™ Cataract Extraction System is a phacoemulsification system which is used by ophthalmic surgeons during cataract surgery. Accessories, which are connected to the consoles, aid the surgeon in breaking up and removing the cataract from the patient's eye. The Sovereign™ Cataract Extraction System is a modification of a previous device and is substantially equivalent to the predicate devices listed above.

Indications for Use:

The intended use of the device is to emulsify and remove cataracts.

Brief summary of nonclinical tests and results:

Performance testing was conducted on the Sovereign™ Cataract Extraction System. Performance in an *in vivo* model system was comparable to the predicate with respect to phacoemulsification, irrigation/aspiration, diathermy, vitrectomy and fluidics. The reusable tubing sets (OPO55) were qualified through cleaning, sterilization and durability studies for up to 20 uses when reprocessed in accordance with the Directions for Use provided.

The results of these tests indicate that Sovereign™ Cataract Extraction System performs equivalent to the predicate devices. The overall function and intended use of the modified device are substantially equivalent to the predicate devices. Therefore, the Sovereign™ Cataract Extraction System is substantially equivalent to the predicate devices in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1998

Marcia S. Yaross, Ph.D.
Director, Worldwide Regulatory Affairs and Medical Compliance
Allergan, Inc.
2525 Dupont Ave.
Irvine, CA 92713-9534

Re: K981116
Trade Name: Sovereign ™ Cataract Extraction System
Regulatory Class: I
Product Code: 86 KYG
Dated: March 26, 1998
Received: March 27, 1998

Dear Ms. Yaross:

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

K981116

ORIGINAL

Indications for Use

510(k) Number (if known): *Unknown at this time*

Device Name: Sovereign™ Cataract Extraction System

Indications for Use:

The Sovereign™ Cataract Extraction System is a phacofragmentation system for use with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract. The Sovereign™ Cataract Extraction System is designed to provide the surgical capabilities desired by the Anterior Segment/Cataract Surgeon for use in the cataract extraction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981116