K971186

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 (714) 752-4500

JUN 13 1997

510(k) Summary
Modified Consoles

1. **Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:**

   a. Allergan
   2525 Dupont Drive
   P.O. Box 19534
   Irvine, California 92623-9534
   (800) 347-4500

   b. Contact Person: Monique M. Heyninck-Duran

   c. Date Summary Prepared: March 31, 1997

2. **Name of device, including trade name and classification name:**

   a. Name of Device: AMO®Diplomax™ and AMO®Opsys® Consoles

   b. Common Name: Phacofragmentation or Phacoemulsification System

   c. Classification Name: As per 21 CFR 886.4670, the product nomenclature is Phacofragmentation System.

3. **Identification of the predicate for legally marketed device or devices to which substantial equivalence is being claimed:**

   a. AMO®Diplomax™ console
   b. AMO®Opsys® console

4. **A description of the device that is the subject of the 510(k), including an explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties).**

   The subject of this 510(k) is the AMO®Diplomax™ and AMO®Opsys® consoles with modified driver controller board, power supply printed circuit board and software. The consoles are part of the 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.

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The design, materials and physical properties of the modified AMO®Diplomax™ and AMO®Opsys® consoles are substantially equivalent to the predicate devices.

5. **Statement of intended use:**

The AMO®Diplomax™ and AMO®Opsys® consoles are designed to provide all the surgical capabilities desired by the Anterior Segment/Cataract Surgeon. Phacofragmentation, also known as phacoemulsification or "phaco," is a cataract removal technique. When utilizing this technique, the surgeon makes a small incision in the eye and breaks up the cataract using ultrasonic vibration delivered by the tip of the handpiece inserted through the incision.

6. **Statement of how the technological characteristics (i.e. design, materials, chemical composition, energy source) compare to the predicate device:**

COMPARISON OF THE SIMILARITIES AND DIFFERENCES BETWEEN THE MODIFIED AND PREDICATE CONSOLES OF THE AMO®DIPLOMAX™ AND AMO®OPSYS® PHACOEMULSIFICATION MACHINES

	Modified AMO®Diplomax™ and AMO®Opsys® Consoles	Predicate AMO®Diplomax™ Console	Predicate AMO®Opsys® Console
Safety Specification	Meets UL 544	Meets UL 544	Meets UL 544
Vitrectomy Circuit Output	Same	Same	Same
Diathermy Circuitry Output	Same	Same	Same
Load Compensation	Yes	Yes	Yes
Output Waveforms	Yes	Yes	Yes
Phaco Output Energy	Yes	Yes	Yes
Continuous Irrigation All Modes	Yes	Yes	Yes
CAP VAC	Yes	Yes	Yes
U/S I/S	Yes	Yes	Yes
Phaco Mode Sound ASP, VAC, U/S	Yes	Yes	Yes
Diathermy Sound	Yes	Yes	Yes
I/A Sound	Yes	Yes	Yes
Self Test	Yes	Yes	Yes

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7. **Brief summary of nonclinical tests and results:**

Performance testing was conducted on the AMO®Diplomax™ console with the Enhanced Driver Board, Power Module PCB and modified software.

The results of these tests indicate that the Enhanced Driver Board and Power Module PCB are compatible when incorporated into the AMO®Diplomax™ and AMO®Opsys® consoles and will not compromise system performance. The modifications incorporated into the modified boards and software do not affect the safety or effectiveness of the console. The overall function and intended use of the modified consoles are substantially equivalent to the predicate devices. Therefore, the consoles with the modified boards are substantially equivalent to the predicate consoles in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Monique M. Heyninck-Duran
Regulatory Affairs Analyst
Allergan
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Re: K971186
Trade Name: AMO®Diplomax™ and
AMO®Opsys® Phacoemulsification Consoles
Regulatory Class: II
Product Code: 86 HQC
Dated: March 31, 1997
Received: April 1, 1997

Dear Ms. Heyninck-Duran:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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

Enclosure

Indications for Use

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

Device Name: AMO®Diplomax™ and AMO®Opsys® Phacoemulsification Consoles

Indications for Use:

The AMO®Diplomax™ and AMO®Opsys® consoles are components of phacofragmentation systems designed to provide all the surgical capabilities desired by the Anterior Segment/Cataract Surgeon. Phacofragmentation, also known as phacoemulsification or "phaco," is a cataract removal technique. When utilizing this technique, the surgeon makes a small incision in the eye and breaks up the cataract using ultrasonic vibration delivered by the tip of the handpiece inserted through the incision.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (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

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