K972063

William F. Whittingham
22 Flores
Foothill Ranch, CA 92610

UltraClean Phaco

William F. Whittingham
Premarket Notification
Whittingham UltraClean Phaco Handpiece

NOV 25 1997

Part D. 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990, and 21 CFR 807.92:

A. Submitter: William F. Whittingham, 22 Flores Rd., Foothill Ranch, California 92610.
Contact: (714) 855-0535; (714) 380-1523 (F).

B. Name of Device: Whittingham UltraClean™ Phaco Handpiece

C. Predicate Device: Allergan Model 5000 Ophthalmic Surgical System

D. Description of the New Device: The Whittingham UltraClean Phaco Handpiece is a phacoemulsification handpiece, for use with standard, disposable phacoemulsification needles, a 39 to 55 KHz Piezoelectric driver module, and the associated ophthalmic surgical system control units. A handpiece such as this is used in ophthalmic surgery to break up (emulsify) and remove unwanted or degenerative tissues, such as cataract tissue.

E. Intended Use: The Whittingham UltraClean Phaco Handpiece is intended for use as a component of a phacoemulsification surgical system, in the surgical removal of unwanted or degenerative tissues, such as cataract tissue.

F. Comparison of Technological Features: The Whittingham UltraClean Phaco Handpiece shares the same general technological characteristics as the predicate device. Both the new and predicate devices are components of a surgical phacofragmentation system which includes attachments and controls for irrigation solutions, and aspiration of tissues and fluids. The standard driver unit operates on 110 v of alternating current. Both phaco handpieces are self cooling, autoclavable, and incorporate a piezoelectric motor operating at 39 to 55 KHz to vibrate an attached phaco needle. Both phaco handpieces accept a standard phaco needle.

Design improvements to the new device include changes that allow 1) the new device to be taken apart for cleaning; 2) the outer shell to be rotated so that attached connectors can be rotated out of the surgeon's line of vision; and 3) the irrigation fluid to be delivered without creating cavitation bubbles, and consequently improving the surgeon's view of the surgical field. These changes are expected to enhance the safety and effectiveness of the device.

Signed,

William F. Whittingham — 8/29/97 date

Phone: (714) 380-1458 Fax: (714) 380-1523

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

Mr. William F. Whittingham
22 Flores
Foothill Ranch, CA 92610

Re: K972063
Trade Name: Whittingham UltraClean™ Phaco Handpiece
Regulatory Class: II
Product Code: 86 HQC
Dated: August 29, 1997
Received: September 4, 1997

Dear Mr. Whittingham:

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

Indications for Use

510(k) Number: K972063

Device Name: Whittingham UltraClean Phaco Handpiece

Indications for Use:

The Whittingham UltraClean Phaco Handpiece is indicated for surgical removal of cataract tissues or other unwanted eye tissue.

Marsha K. Burke Nicholas
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)