K990292

NOV 19 1999

Ophthalmic Consultants, Inc.

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Kirkland WA 98033

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
[As Required by21 CFR 807.92(c)]

Date prepared: August 11, 1999

01. Submitter (and specification developer):	Ophthalmic Consultants, Inc. P O Box 2728 (10815 106th Avenue Northeast Kirkland WA 98083-2728
Kit Packer:	Medical Techniques, LC 125 N. 400 West North Salt Lake UT 84054
Sterilizer:	Griffith Micro Science - Salt Lake City facility 5725 W. Harold Gatty Road Salt Lake City UT 84116
02. Contact Person:	Timothy Barker President/CEO, Director of Sales/Marketing
Telephone:	425-803-6868
03. Trade names:	Phacoemulsification Pack Anterior Vitrector Pack Anterior Collection Cassette Posterior Vitrector Pack Posterior Collection Cassette Filtered Irrigation Administration Set
04. Common names:	Phacoemulsification Pack Anterior Vitrector Pack Anterior Collection Cassette Posterior Vitrector Pack Posterior Collection Cassette Filtered Irrigation Administration Set

05. Classification nme(s): ~~Ophthalmic Kits~~ Accessories to Vitreous aspiration and Cutting Instruments

06. Product Code: ~~Unclassified, 86-series~~ 86 HQF accessories

Device Class: Class II

07. Performance Standards: No performance standards have been officially adopted by the FDA.

08. Predicate Devices: The above packs are substantially equivalent to K980100, K962131, K961874, K961831, K955901, K953575, and K913504, et al, all of which were determined to be SE.

09. Description: Ophthalmic surgical kits/packs containing components used for irrigation/aspiration, anterior and posterior vitrectomies, phacoemulsification, and or administration of fluids.

10. Intended Use:

To provide single-use components to be used in conjunction with a facility's existing compatable equipment, in one convenient kit/pack, for ophthalmic surgical procedures, used in accordance with the equipment manufacturer's instructions, performed by a certified clinician in a clinical setting, as follows:

(1) Phaco Emulsifier Pack: Provides the irrigation and aspiration tubing/ administration sets and equipment covers/drapes used in anterior, e.g., cataract, surgical procedures;
(2) Anterior Vitrectomy Pack: Provides the vitrector, surgical blade, scleral plugs for incision patency, and 10 cc syringe and fluid irrigation and aspiration tubing/administration sets, and equipment covers/drapes, used in anterior surgical procedures;
(3) Anterior Collection Cassette: Provides the fluid collection cassette and tubing for the collection and disposal of fluids during ophthalmic anterior surgical procedures;
(4) Posterior Vitrectomy Pack: Provides the vitrector, surgical blade, scleral plugs for incision patency, and 10 cc syringe and fluid irrigation and aspiration tubing/administration sets, and equipment covers/drapes, used in posterior segment, e.g., retinal, surgical procedures;
(5) Posterior Collection Cassette: Provides the fluid collection cassette and tubing for the collection and disposal of fluids during ophthalmic posterior surgical procedures.
(6) Filtered Irrigation Administration Set: Provides commonly used tubing sets for the filtering and administration of fluids for flushing/irrigating a surgical site during either posterior or anterior ophthalmic procedures.

11. Summary of Technological Characteristics of These Packs Compared to the Predicates:

There are no substantive changes in materials, basic components (the majority of which have their own 510(k)'s, or method of manufacture or sterilization between these devices and their predicates.

12. Summary of Nonclinical Tests and Results:

The packs' components have been tested by an independent lab for biocompatability (cyctotoxicity, hemolysis) with no problems noted. Both components and packs will be subjected to QC upon receipt, during/after manufacture, and prior to release.

13. Conclusion:

The function and use of these packs and their components are no different than that of the predicates, as well as other similar devices, packs as well as individual components, marketed since pre-amendment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Mr. John E. Lincoln
Consultant to Ophthalmic Consultants, Inc.
J.E. Lincoln and Associates
65 North Main
Suite 101
P.O. Box 154
Toole, UT 84074

Re: K990292
Trade Name: Ophthalmic Consultants, Incorporated's
Phacoemulsification Pack
Posterior Collection Cassette Pack
Anterior Collection Cassette Pack
Posterior Vitrectomy Pack
Anterior Vitrectomy Pack
Administration Disposable Pack
Regulatory Class: II
Product Code: 86 HQE
Dated: August 19, 1999
Received: August 23, 1999

Dear Mr. Lincoln:

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 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). 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): K990292

Device Name: Ophthalmic Kits/Packs

Indications For Use:

To provide single-use components to be used in conjunction with a facility's existing compatable equipment, in one convenient kit/pack, for ophthalmic surgical procedures, used in accordance with the equipment manufacturer's instructions, performed by a certified clinician in a clinical setting, as follows:

01. Phaco Emulsifier Pack: Provides the irrigation and aspiration tubing/ administration sets and equipment covers/drapes used in anterior, e.g., cataract, surgical procedures;
02. Anterior Vitrectomy Pack: Provides the vitrector, surgical blade, scleral plugs for incision patency, and 10 cc syringe and fluid irrigation and aspiration tubing/administration sets, and equipment covers/drapes, used in anterior surgical procedures;
03. Anterior Collection Cassette: Provides the fluid collection cassette and tubing for the collection and disposal of fluids during ophthalmic anterior surgical procedures;
04. Posterior Vitrectomy Pack: Provides the vitrector, surgical blade, scleral plugs for incision patency, and 10 cc syringe and fluid irrigation and aspiration tubing/administration sets, and equipment covers/drapes, used in posterior segment, e.g., retinal, surgical procedures;
05. Posterior Collection Cassette: Provides the fluid collection cassette and tubing for the collection and disposal of fluids during ophthalmic posterior surgical procedures.
06. Filtered Irrigation Administration Set: Provides commonly used tubing sets for the filtering and administration of fluids for flushing/irrigating a surgical site during either posterior or anterior ophthalmic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRB Nicholas

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990292

Prescription Use XX OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)