K970727

Summary of Safety and Effectiveness

DEC 17 1997

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

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

   a. Chiron Vision Corporation
   555 West Arrow Highway
   Claremont, California 91711

   b. Contact Person: Judy F. Gordon, D. V. M.
   Senior Vice President, Research and Development

   Jan Champion for

   c. Date Summary Prepared: November 5, 1997

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

   a. Trade/Proprietary Name: Mport™ Foldable Lens Placement System

   b. Classification Name: Intraocular Lens Guide

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

   Company: Chiron Vision Corporation

   Device: Microsert™ Foldable Lens Placement System

   510(k) K914311

   Date Cleared June 2, 1995

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

The Mport™ Foldable Lens Placement System is a device designed to compress and insert a Soflex™ multipiece foldable intraocular lens into the eye during normal small incision cataract surgery. The Mport™ is a single use only disposable device. The Mport™ materials the same as those materials used in the lens/patient contacting cartridge of the predicate device (polypropylene).

5. Statement of intended use:

The Mport™ Foldable Lens Placement System is intended to be used to compress and insert a Soflex™ multipiece intraocular lens into the capsular bag.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Comparative Technological Characteristics

CHARACTERISTICS	MICROSERT™ (PREDICATE)	MPORT™
Intended Use	Folds and delivers a Soflex™ IOL into the eye during normal small incision cataract surgery	Same
Operating Principle	• Loads IOL into the inserter mechanically and inserts IOL into the eye. • IOL delivered by rotating a screw device creating forward motion.	• Same • IOL delivered by direct forward motion applied to a syringe-type plunger
Folding Operation (Refer to comparison pictures in Section 9 and Directions for Use in Section 7)	IOL is loaded into cartridge and closed. Apposing contact edges are folded toward each other.	IOL is loaded flat in unstressed state and laterally compressed by the closure of a slider. Contact edges are maintained in the same plane.
Folding direction of the lens	Lens unfolds facing up (taco up)	Lens decompresses in a horizontal plane
Cartridge design	Single-piece (insertion chamber)	None

continued

CHARACTERISTICS	MICROSERT™ (PREDICATE)	MPORT™
Sterilization method	EO for cartridge and accepted surgical method for inserter handpiece.	EO for entire device
Materials	• Polypropylene disposable cartridge • Titanium reusable handpiece.	• Polypropylene disposable tube, slide pusher and jackets. • Silicone o-ring
Surface treatment	None	None
*Patient contact portion of device	Cartridge tip and handpiece tip	Tube tip and pusher tip

7. Brief summary of nonclinical tests and results:

The Mport™ Foldable Lens Placement System was found to be acceptable for delivery of Chiron's Soflex™ multi-piece lenses. The use of the Mport™ for delivery of Soflex lenses has no impact on lens diopter, resolution or cosmetic appearance of the lens when used in accordance with the directions for use. Optical specifications measured before and after lens delivery showed no negative impact to the lens from the use of the Mport™ delivery system. Biocompatibility testing and sterilization studies support the fact that the technological changes in the Mport™ system do not raise any new issues of safety, effectiveness or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

Judy F. Gordon, D.V.M.
Senior Vice President, Research
and Development
Chiron Vision Corporation
555 West Arrow Hwy.
Claremont, CA 91711

Re: K970727
Trade Name: Mport™ Foldable Lens Placement System
Regulatory Class: I
Product Code: 86 MSS
Dated: November 5, 1997
Received: November 6, 1997

Dear Dr. Gordon:

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

510(k) Number (if known): K970727

Device Name: **Mport™, Foldable Lens Insertion System**

Indications for Use:

The Mport™ Foldable Lens Placement System is a Class I device indicated for compressing and inserting a Soflex™ (formerly Chiroflex II) series multi-piece intraocular lens into the eye during small incision cataract surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna Lochner
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K970727

Prescription Use X **OR** **Over-The-Counter Use** ____

(Per 21 CFR 801.109)