K972661

510(k) SUMMARY

OCT - 3 1997

as required per 807.92(c)

2: Submitters Name, Address:

Gulden Ophthamics, Inc
225 Cadwalader Drive
Elkins Park, Pa 19027

Telephone: (215) 884-8105 Fax: (215) 884-0418
Official Correspondent: Mr. Thomas Cockley

Date submission was prepared: July 7, 1997
Establishment Registration Number: 2519410

3: Trade Name, Common Name and Classification Name:

A. Trade Name:

Eye Sphere – Sterile
Conformer - Sterile

B. Common Name, Classification Number, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Implant, Eye Sphere	86HPZ	II	886.3320
Conformer, ophthalmic	86HQN	II	886.3130

4: Predicate Device Identification:

Eye Sphere – Non Sterile	Gulden Ophthalmics, Elkins Park, PA	Pre-amendment
Eye Sphere – Sterile	Storz Instruments, St. Louis, Mo	K921106
Conformers – Non Sterile	Gulden Ophthalmics, Elkins Park, PA	Pre-amendment
Conformers – Sterile	Storz Instruments, St. Louis, Mo	K921106

5. Device Description:

Eye Spheres: Eye spheres are permanent implants that occupy the eye cavity when it has become necessary to surgically remove the eye (enucleation) or the contents of the eye sac (evisceration).

Conformers: Conformers are temporary devices that maintain the shape of the eye and prevent closure or adhesion during the healing process.

6. Intended Use:

Eye Spheres: To occupy the eye cavity when it has become necessary to surgically remove the eye (enucleation) or the contents of the eye sac (evisceration).

Conformers: To maintain the shape of the eye and prevent closure or adhesion during the healing process.

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7. Table of device similarities and differences to predicate device

	Substantial Equivalence Gulden Ophthalmics Eye Spheres – Non Sterile Conformers – Non Sterile	Substantial Equivalence Storz Ophthalmics Eye Spheres – Sterile Conformers – Sterile	Gulden Ophthalmics Eye Spheres – Sterile Conformers – Sterile
Manufacturer	Gulden Ophthalmics	Manufactured for Storz Instruments by Gulden Ophthalmics	Gulden Ophthalmics
510K Number	Pre-amendment	K921106	New
FDA Product Class	Class II	Same	Same
Intended Population	Pediatric and Adult	Same	Same
Material	Polymethylmethacrylate (PMMA)	Same	Same
Size Range – Eye spheres	8, 10, 12, 14, 16, 18, 20 and 22 mm	Same	Same
Size Range - Conformers	Small, Medium, Large	Same	Same
Method of sterilization	None	EtO (88%)	EtO(100%) and Gamma Sterilization

8. Assessment of non-clinical performance data for equivalence: The Gulden Ophthalmics "sterile" eye spheres and "sterile" conformers are exactly the same as the eye spheres and conformers sold as "non-sterile" by Gulden Ophthalmics. Gulden supplies Storz Instruments with Gulden's "non-sterile" eye spheres and conformers. Storz Instruments sterilizes these products with Ethylene Oxide (EtO) and distributes them as "sterile". Gulden proposes to offer for sale the same eye spheres and conformers as sterile.

9. Assessment of clinical performance data for equivalence: Not applicable. These products have been in commercial distribution since before July 1976 and are generally regarded as safe.

10. Biocompatability: PMMA: Generally Regarded as Safe

11. Sterilization:

A. ETO. 100% Ethylene Oxide

Temperature	130 ±5 ° F / ± 3 ° C
Pre-Vacuum	24" – 26" inHg / 610 – 660 mmHg
Relative Humidity	60 ± 10 % RH
Humidity Dwell	30 – 45 minutes
Sterilant Gas	Ethylene Oxide, 100%
EO Concentration	600 ± 30 mg/l
Exposure Time	2 hours ± 5 minutes
Post Vacuum	24" – 26" / 610 – 660 mmHg (2 times)
Mechanical Aeration temp.	110 – 124 ° F / 43 – 51° C
Aeration time	48 Hours (minimum) 72 Hours (Recommended)

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B. Gamma Radiation
   1. Bioburden Studies per ANSI/AAMI/ISO 11737-1-1995, "Sterilization of Medical devices-Microbiological Methods-Part 1: Estimation of population of microorganisms on product" AAMI Method 1
   2. Gamma Sterilization at dose validated by bioburden studies
   3. Each lot to be validated rather than routine monitoring studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas Cockley
President
Gulden Ophthalmics
225 Cadwalader Avenue
Elkins Park, PA 19117-2097

OCT - 3 1997

Re: K972661
Trade Name: Eye Sphere and Conformer
Regulatory Class: II
Product Code: 86 HPZ and 86 HQN
Dated: July 7, 1997
Received: July 16, 1997

Dear Mr. Cockley:

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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Indicated Use Statement

Eye Spheres: Eye spheres are permanent implants that occupy the eye cavity when it has become necessary to surgically remove the eye (enucleation) or the contents of the eye sac (evisceration).

Conformers: Conformers are temporary devices which maintain the shape of the eye and prevent closure or adhesion during the healing process.

Donna Lechner

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972661

Prescription Use X
(Per 21 CFR 801.109)