510(k) Summary

Submitter's Name	Product and Educational Services LLC
Address	Bucks County Biotechnology Center 3805 Old Easton Road Doylestown, PA 18902 Phone: (215) 230 7515 Facsimile: (215) 230 7517
Contact Person	Edward T. Griffith President
Date of Summary:	26 September 2008
Proprietary Name of Device:	None
Common/Usual Name:	Eye Sphere Conformer
Classification Name:	Implant, Eye Sphere Conformer, Ophthalmic

Legally Marketed Equivalent Devices:

Gulden Ophthalmics Eye Sphere and Conformer (K972661)

Summary of Device:

When an eye is severely damaged by trauma or disease, it may be necessary to remove it surgically. The most common procedures are evisceration (removal of the contents of the eye) or enucleation (removal of the eye itself). Eye spheres are permanent implants to occupy the cavity that results from surgery. Conformers are temporary devices, which maintain the shape of the eye and prevent closure or adhesion during the healing process. When healing is complete, conformers are replaced with prosthesis. Eye Spheres and Conformers are made of polymethylmethacrylate (PMMA), a hard, clear plastic that is lightweight, inert and virtually unbreakable. Eye spheres are available in even diameters from 10mm through 22mm. Conformers are available in three sizes: small, medium, large. Conformers may be ordered with or without holes. Eye spheres and Conformers are FDA Class II products.

Intended Use:

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

Technological Characteristics of the Device Compared to the Predicate Devices:

	Gulden Ophthalmics Eye Spheres – Non Sterile Conformers – Non Sterile	Gulden Ophthalmics Eye Spheres – Sterile Conformers – Sterile	Product and Educational Services LLC Eye Spheres - Sterile Conformers - Non Sterile
Manufacturer	Gulden Ophthalmics	Gulden Ophthalmics	Product and Educational Services LLC
510K Number	Pre-amendment	K972661	New
FDA Product Class	Class II	Class II	Class II
Intended Population	Pediatric and Adult	Pediatric and Adult	Pediatric and Adult
Material	Polymethylmethacrylate (PMMA)	Polymethylmethacrylate (PMMA)	Polymethylmethacrylate (PMMA)
Size Range (mm) – Eye Sphere	10, 12, 14, 16, 18, 20, and 22 mm	10, 12, 14, 16, 18, 20, and 22 mm	10, 12, 14, 16, 18, 20, and 22 mm
Size Range – Conformers	Small, Medium, Large (with and without holes)	Small, Medium, Large (with and without holes)	Small, Medium, Large (with and without holes)
Method of sterilization	None	EtO (100%) and Gamma Sterilization	Gamma Sterilization only

K082850

Non-Clinical Tests:

Product and Educational Services LLC (PES) Eye Spheres and Conformers are the same Eye Spheres and Conformers manufactured and marketed by Gulden Ophthalmics as "non sterile". The only difference is that PES will be providing the same Eye Spheres and Conformers as sterile, single use devices. Gulden Ophthalmics Eye Spheres and Conformers are "pre-amendment" devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Product and Educational Services, LLC
PA Biotechnology Center of Bucks County
Mr. Edward T. Griffith
President
3805 Old Easton Road
Doylestown, PA 18902

FEB 27 2009

Re: K082850
Trade Name: Eye Spheres and Conformers
Regulation Number: 21 CFR 886.3320
Regulatory Class: II
Product Code: HPZ, HQN
Dated: February 12, 2009
Received: February 17, 2009

Dear Mr. Griffith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082850

Device Name: Eye Spheres and Conformers

Indications for Use:

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

Prescription Use ___1___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K082850