K070130

APR 19 2007

2.0 510(K) SUMMARY FOR THE ORBITAL RECONSTRUCTIVE IMPLANT

Submission Date: January 16, 2006

Submitter Information:

Company Name: **Evera Medical, Inc.**

Company Address: 353 Vintage Park Drive
Suite F
Foster City, CA 94404

Contact Person: Michael D. Lesh, MD
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Device Information:

Trade Name: Orbital Reconstructive Implant (ORI)

Common Name: Orbital Implant

Classification Name: 21 CFR § 886.3320

Classification Code: HPZ

Device Class: Class II

Predicate Device(s):

Trade Name: Medpor Plus Orbital Volume Replacement Implant
Manufacturer: Porex Surgical, Inc.
K Number: K021357
Product Code: HPZ

Trade Name: Eye Sphere Conformer
Manufacturer: Gulden Ophthalmics
K Number: K972661
Product Code: HPZ / HQN

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Trade Name:	Orbital Tissue Expander
Manufacturer:	Innovia LLC
K Number:	K060151
Product Code:	NFM
Trade Name:	Oculo-Plastik Universal-ePTFE
Manufacturer:	Oculo-Plastik, Inc.
K Number:	K934834
Product Code:	HPZ

Device Description: The ORI is a non-absorbable, inert, sterile, porous, surgical implant composed of silicone elastomer and expanded polytetrafluoroethylene (ePTFE). If desired, the thickness of the ORI can be augmented by adding a small volume of saline prior to implantation. This polymeric implant is available in a range of lengths, widths and thicknesses to accommodate the surgical application and the needs of the individual surgeon practicing medicine.

Intended Use: The ORI is intended for augmentation or restoration and to separate tissues.

Indications for Use: The ORI is indicated as an implant for augmentation, reconstruction, or restoration in and around the orbit of the eye, such as in reconstruction following orbital trauma or tumor excision, to treat orbital volume deficiencies, or in the correction of enophthalmos. The ORI is also indicated as a temporary device to maintain the shape of the eye and prevent closure or adhesion during the postoperative period.

Comparison to Predicate Device: The ORI has the same intended use and technological characteristics as the predicate devices. Slight differences in design and performance from the cited predicates do not affect either the safety and/or effectiveness of the ORI for its intended use. The safety and effectiveness evaluations based on biocompatibility and biomechanical performance data provided in this 510(k) demonstrate that the ORI is substantially equivalent to the cited predicate devices.

Conclusion: The results of these evaluations of the ORI support the conclusion that it is safe and effective for its intended use and that it is substantially equivalent to the cited predicate device(s) with regards to its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Becker & Associates Consulting, Inc.
c/o Ms. Campbell Tuskey
Project Manager
2001 Pennsylvania Ave NW
Washington DC 20006

APR 19 2007

Re: K070130
Trade Name: Orbital Reconstructive Implant (ORI)
Regulation Number: 21 CFR 886.3320
Regulation Name: eye sphere implant
Regulatory Class: Class II
Product Code: HPZ
Dated: March 26, 2007
Received: March 26, 2007

Dear Ms. Tuskey:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K070130

Device Name: Orbital Reconstructive Implant

Indications for Use:

The Orbital Reconstructive Implant is indicated as an implant for augmentation, reconstruction, or restoration in and around the orbit of the eye, such as in reconstruction following orbital trauma or tumor excision, to treat orbital volume deficiencies, or in the correction of enophthalmos. The ORI is also indicated as a temporary device to maintain the shape of the eye and prevent closure or adhesion during the postoperative period.

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he / she practices to use or order the use of the device.

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070130