K083342

MAR 12 2009

2.0 510(K) SUMMARY FOR THE ORBITAL RECONSTRUCTIVE IMPLANT II

Submission Date: November 7, 2008

Submitter Information:

Company Name: Evera Medical, Inc.

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

Contact Person: Randy Kesten
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randy.kesten@everamedical.com

Device Information:

Trade Name: Orbital Reconstructive Implant II (ORI II)

Common Name: Orbital Implant

Classification Name: 21 CFR § 886.3320

Classification Code: HPZ

Device Class: Class II

Predicate Device(s):

Trade Name: Orbital Reconstructive Implant
Manufacturer: Evera Medical, Inc.
K Number: K070130
Product Code: HPZ

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

Trade Name: Oculo-Plastik Universal-ePTFE
Manufacturer: Oculo-Plastik, Inc.
K Number: K934834

Product Code:	HPZ
Trade Name:	Solid Silicone and Silicone Foam Implants
Manufacturer:	MIRA, Inc.
K Number:	K950806
Product Code:	HQX

Device Description:

The Orbital Reconstructive Implant II (ORI II) is a non-absorbable, inert, sterile, porous, implant composed of porous silicone elastomer and expanded polytetrafluoroethylene (ePTFE). This polymeric implant is available in a range of lengths and widths to accommodate the surgical application and the needs of the individual surgeon practicing medicine.

Intended Use:

The ORI II is intended for augmentation or restoration in the craniofacial region.

Indications for Use:

The ORI II 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.

Comparison to Predicate Device:

The ORI II 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 II for its intended use. As compared to the ORI predicate (K070130), ORI II uses the same materials in its construction: polydimethylsiloxane elastomer ("silicone elastomer") and expanded polytetrafluoroethylene. The slight design difference between ORI II and the ORI predicate is that the silicone elastomer is processed to form a porous core layer of the implant, while in ORI the silicone was formed into a film core of the implant. The slight performance difference between ORI II and the ORI predicate is that ORI II exhibits approximately 50% greater tensile strength than ORI, while the elongation at break of ORI II is approximately 25% of that of ORI.

Non-clinical performance data demonstrated in bench testing of ORI II are substantially equivalent to those of the predicates. The following testing was performed to measure the performance of ORI II as compared to the predicate devices: Tensile load at break; Tensile elongation at break; Elastic (Young's) modulus; Compression deflection; Uniaxial compressive modulus; Compressive set; Suture pullout; Shear modulus; Ultimate shear strength; and Shear load at break. Where applicable, test methods used the following testing standards: ASTM-D624; ASTM-D1777; ASTM-F88; ASTM-D412; and ASTM-D3787. The results of this testing showed that ORI II was demonstrated to be safe and effective for its intended use. ORI II will be manufactured in accordance with the product performance specifications derived from these test results.

The biocompatibility of ORI II was evaluated based on the long-term implant section of the ISO-10993 standard and shown to be biocompatible.

The safety and effectiveness evaluations based on biocompatibility and biomechanical performance data provided in this 510(k) demonstrate that the ORI II is substantially equivalent to the cited predicate devices.

Conclusion:

The results of these evaluations of the ORI II 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

MAR 12 2009

Evera Medical, Inc.
c/o Randy Kesten
Chief Technical Officer
1191 Chess Drive, Suite G
Foster City, CA 94404

Re: K083342
Trade/Device Name: Orbital Reconstructive Implant II (ORI II)
Regulation Number: 21 CFR 886.3320
Regulation Name: Implant, Eye Sphere
Regulatory Class: II
Product Code: HPZ
Dated: February 10, 2009
Received: February 12, 2009

Dear Mr. Kesten:

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,

Malvina B. Eydelman, M.D.

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

1.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K083342

Device Name: Orbital Reconstructive Implant II

Indications for Use:

The Orbital Reconstructive Implant II 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.

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)

Mary L. Kaufman

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

510(k) Number K083342

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