K003338

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ADMINISTRATIVE INFORMATION

Manufacturer Name: Integrated Orbital Implants, Inc.
12526 High Bluff Dr., Suite 300
San Diego, CA 92130-2067

Official Contact: Arthur C. Perry, M.D., F.A.C.S.
Telephone (858) 792-3565
Fax (858) 259-6277

Representative/Consultant: Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Name: Sphere, eye implant

Trade/Proprietary Name: Bio-eye® II Orbital Implant

Common Name: Orbital or ocular implant

ESTABLISHMENT REGISTRATION NUMBER: 2027377

DEVICE CLASSIFICATION

In the Federal Register of January 26, 1982 [FR 47 page 3694], FDA proposed that eye sphere implants be assigned to Class II, as shown in 21 CFR 886.3320. Eye sphere implants are reviewed by the Ophthalmic section of the Surgical and Rehabilitation Devices Panel, and have been assigned Product Code 86HPZ. Wraps for eye sphere implants are classified under the same CFR reference, and have been assigned Product Code 86MTZ.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the IOI Bio-eye II Orbital Implant complies include American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.

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PACKAGING/LABELING/STERILIZATION

The Bio-eye II Orbital Implant is packaged in an Ethylene Oxide (EtO) sterilizable package consisting of a primary heat sealed chevron pouch containing a similar secondary heat sealed chevron pouch. Sterilization is accomplished by treatment in 100% ethylene oxide. Sterilization will be validated using ANSI/AAMI/ISO 11135, *Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization*. The implant will be verified to have a residual ethylene oxide or ethylene chlorhydrin content not greater than 250 ppm, based on the mass of the implant. Residual levels will be determined by complete extraction of the implant in solvent (THF, chloroform, or methylene chloride) and analysis by GC. Methods will all be validated according to ANSI/AAMI/ISO 10993-7. The sterility assurance level (SAL) that IOI intends to meet for the Bio-eye II Orbital Implant is 10^{-6}. The device is not represented to be "pyrogen free."

INTENDED USE

The Bio-eye II Orbital Implant is indicated in orbital implantation following enucleation or evisceration, or as a secondary orbital implant following extrusion, migration or rotation of primary orbital implants. The Bio-eye II Orbital Implant is indicated in any situation where materials such as silicone, acrylic, polyethylene or glass orbital implants would be used. The bioabsorbable polymer coating of the implant makes the supplemental use of wrapping material (such as sclera, bovine pericardium, etc.) unnecessary.

DEVICE DESCRIPTION

Design Characteristics

Hydroxyapatite orbital implants are commonly used to replace the globe following enucleation or evisceration. The implant is integrated into the soft tissues of the anophthalmic socket by fibrovascular ingrowth, providing the advantages of enhanced prosthesis motility, a decrease in migration rate and theoretical protection from infection. To facilitate insertion and to reduce the possibility of exposure of the implant, a wrapping material is frequently used. The most common wrap is homologous donor sclera, but materials such as autologous temporalis fascia and fascia lata, bovine pericardium, expanded poly(tetrafluoroethylene) (EPTFE) and poly(lactide-co-glycolide) (Vicryl) mesh have also been used.

The subject of this submission, the Bio-eye II Orbital Implant, applies the principle of the predicate Ocu-Guard orbital implant wrap to the predicate Bio-eye Orbital Implant. It combines, in a single device, the hydroxyapatite sphere and a preformed wrap of bioabsorbable polymers

that covers the implant, thus facilitating insertion of the implant into the orbit and attachment of rectus muscles to the implant.

The hydroxyapatite implant is a spherical implant, generally of 16 mm to 22 mm. It is a porous, naturally derived implant that is similar in composition to the mineral portion of human bone. The macrostructure and microstructure of the Bio-eye II Orbital Implant are characterized by a unique interconnected matrix of pores. Products with nominal pore diameter of 200μm and 500μm are available. The hydrothermal manufacturing process converts the calcium carbonate exoskeleton of coral to hydroxyapatite (calcium phosphate), while preserving the structure of the coral exoskeleton.

The wrap is fabricated from a thin sheet of bioabsorbable polymers. Small "windows" in the posterior portion of the implant facilitate ingrowth of soft tissue and blood vessels. Windows may also be cut in more anterior locations to facilitate attachment of the rectus muscles and further enhance tissue ingrowth.

Material Composition

The hydroxyapatite component of the Bio-eye II Orbital Implant is made from high purity hydroxyapatite, derived from coral as discussed above.

The bioabsorbable polymer portion of the Bio-eye II Orbital Implant is made up of two polymer compositions. The anterior portion is made from a relatively slowly absorbing polylactide (PLA). It is intended to retain its strength for sufficient time to allow muscle attachment to and ingrowth into the implant before losing strength. *In vitro* experiments with suture retention show that the polymer retains its strength longer than does the suture that is used to attach the muscle. The posterior portion of the implant wrap is made of a more rapidly absorbing poly(lactide-co-glycolide). In combination with windows cut in the implant during manufacture and/or by the surgeon, this portion of the implant wrap is designed to allow relatively rapid ingrowth of soft tissue and vascularity.

EQUIVALENCE TO MARKETED PRODUCT

Integrated Orbital Implants believes that the Bio-eye II Orbital Implant is substantially equivalent to the Bio-eye Orbital Implant (K891137 and K982562) and, in particular, to its use in conjunction with a wrap such as Ocu-Guard or Ocu-Guard Supple, from Bio-Vascular, Inc. (K973552 and K983581) or EPTFE Sheet Covering for Ocular Implant, from Oculo Plastik, Inc. (K934834). Information on predicate devices is shown in Exhibit V. The Bio-eye II Orbital Implant is also equivalent to the use of the Bio-eye implant with a wrap of Vicryl knitted mesh, the patient's own temporalis fascia or fascia lata, Tutoplast or freeze dried dura.

Intended Uses

The indications for use for the Bio-eye II Orbital Implant and the principal predicate device, the Bio-eye Orbital Implant are identical. Both are intended for use in orbital implantation following enucleation or evisceration, or as a secondary orbital implant following extrusion, migration or rotation of primary orbital implants. The additional predicate devices, Ocu-Guard and the EPTFE wrap, are intended to supplement the hydroxyapatite and facilitate insertion, in the same way as the polymer wrap used on the Bio-eye II Orbital Implant.

Design and Materials

The design and functional characteristics of the Bio-eye II Orbital Implant are the same as those of the Bio-eye Orbital Implant when it is used in conjunction with Ocu-Guard, EPTFE wrap, donor sclera, Vicryl mesh, temporalis fascia or fascia lata. The wrap covers the implant during insertion and initial healing in order to facilitate insertion and to reduce the possibility of exposure of the implant.

Mechanical Testing of Bio-eye II Orbital Implant

Because a suture is intended to be attached to the anterior segment of the Bio-eye II Orbital Implant in order to secure extraocular muscles, testing was done to ensure that the film is capable of retaining a Vicryl suture, as is presently used, under load until failure of the suture.

Biocompatibility of Bioabsorbable Polymers

A review of literature on bioabsorbable polymers, including investigations of biocompatibility, strongly supports the conclusion that the materials used for the Bio-Eye II implant are biocompatible and non-toxic materials that are safe to use for implantable medical devices.

Rabbit Study of Bio-eye Orbital Implants Coated with Bioabsorbable Polymer

In order to test the response of orbital soft tissues to the more rapidly bioabsorbable of the polymers used for the Bio-eye II Orbital Implant during initial healing, polymer-coated hydroxyapatite implants and uncoated hydroxyapatite implants (control) were surgically implanted in enucleated orbits of New Zealand white rabbits for four and eight weeks. Following the implantation period, animals were euthanized and the implants were explanted and examined histologically. There was no evidence of an unusual healing response or tissue reaction in either the polymer-coated or control group of implants, with no negative tissue effect attributable to the polymer coating.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

Integrated Orbital Implants, Inc. believes that the Bio-eye II Orbital Implant is substantially equivalent to the Bio-eye Orbital Implant (K891137 and K982562) and, in particular, to its use in conjunction with a wrap such as Ocu-Guard or Ocu-Guard Supple, from Bio-Vascular, Inc. (K973552 and K983581) or EPTFE Sheet Covering for Ocular Implant, from Oculo Plastik, Inc. (K934834):

	Subject Device	**Predicate Devices**		
	Bio-eye II Orbital Implant	Bio-eye Orbital Implant, Integrated Orbital Implants (K891137, K982562)	Ocu-Guard, Ocu-Guard Supple, Bio-Vascular (K973552, K983581)	EPTFE Sheet, Oculo Plastik (K934834)
INTENDED USE				
	Intended to be used as a primary implant in cases of enucleation or evisceration, or as a secondary implant in cases of poor performance of a primary implant, such as in cases of poor motility, migration, extrusion, chronic infection, enophthalmos, and lid sag. The device is indicated in any situation where silicone, acrylic, polyethylene, glass, or other traditional orbital implants are used.	Intended to be used as a primary implant in cases of enucleation and evisceration, and as a secondary implant in cases of poor performance of a primary implant, such as in cases of poor motility, migration, extrusion, chronic infection, enophthalmos, and lid sag. The device is indicated in any situation where silicone, acrylic, polyethylene, glass, or other traditional orbital implants are used.	Intended for wrapping of orbital implants used in enucleation surgeries	Intended for wrapping of orbital implants used in enucleation surgeries
DESIGN				
	Porous hydroxyapatite sphere with bioabsorbable polymer coating	Porous hydroxyapatite sphere	Wrap intended for hydroxy-apatite orbital implant	Wrap intended for orbital implant
MATERIAL				
Implant	Hydroxyapatite	Hydroxyapatite		
Coating or wrap	Bioabsorbable polymers		Bovine pericardium, glutaraldehyde crosslinked	Expanded PTFE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Integrated Orbital Implants, Inc.
c/o Mr. Floyd G. Larson
Paxmed International
4329 Graydon Road
San Diego, CA 92130

Re: K003338
Trade Name: Bio-eye ® II Orbital Implant
Regulatory Class: II
Product Code: 86 HPZ and MTZ
Dated: January 2, 2001
Received: January 4, 2001

Dear Mr. Larson:

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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Device Name: Bio-eye® II Orbital Implant

Indications for Use:

The Bio-eye II Orbital Implant is indicated in orbital implantation following enucleation, or as a secondary orbital implant following extrusion, migration or rotation of primary orbital implants. It is indicated in any situation where materials such as silicone, acrylic, polyethylene or glass orbital implants would be used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003338

Prescription Use X OR Over-The-Counter Use____