

DEC 28 1998

K 982562



INTEGRATED ORBITAL IMPLANTS, INC.

**510(k) SUMMARY as required by 807.92(c)
Bio-eye® Hydroxyapatite Ocular Implant and Conformer**

1. SUBMITTER'S NAME, ADDRESS, TELEPHONE AND FAX NUMBER:

Integrated Orbital Implants, Inc.
12526 High Bluff Dr., Suite 300
San Diego, CA 92130-2067
Telephone: 619-792-3565
Fax: 619-259-6277

CONTACT PERSON:

Jeanne Dunham, President
Bioserv Corporation
Telephone: 619-450-3123
Fax: 619-450-0785

*5340 Eastgate Mall
San Diego, CA 92121*

DATE SUMMARY PREPARED: July 10, 1998

2. NAME OF DEVICE:

PROPRIETARY NAME: Bio-eye® Hydroxyapatite Ocular Implant and Conformer
COMMON/USUAL NAME: Eye sphere implant
Ophthalmic Conformer
CLASSIFICATION NAME: Eye sphere implant, 21 CFR 886.3320, Class II
Ophthalmic conformer, 21 CFR 886.3130, Class II

3. PREDICATE DEVICE:

Motility Orbital Implant K891137
Ophthalmic Conformer K945110 (510(k) exempt Federal Register 1-21-98)
Interpore 200 Porous Hydroxyapatite K860983.

4. DESCRIPTION OF DEVICE: Both the Motility Orbital Implant and the Bio-eye Hydroxyapatite Ocular Implant are eye sphere implants manufactured of hydroxyapatite. The Bio-eye Hydroxyapatite Ocular Implant will now be provided sterile. The Ophthalmic Conformer is used in conjunction with the Ocular Implant for ocular prosthesis and will also be supplied sterile.

5. INTENDED USE: The Bio-eye Hydroxyapatite Ocular Implant is intended to be implanted in the eyeball to occupy space following removal of the contents of the eyeball. The Ophthalmic Conformer is intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity during the healing process following surgery.



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**Bio-eye® Hydroxyapatite Ocular Implant and Conformer
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6. **TECHNOLOGICAL CHARACTERISTICS:** The technological characteristics of the Ocular Implant are the same as the predicate: Both Implants are manufactured of porous hydroxyapatite. It is a synthetic hydroxyapatite which is similar in composition to the mineral content of human bone. The implant material has a unique interconnected porous matrix derived from specific marine corals. A patented manufacturing process preserves the porous structure of the coral while the calcium carbonate skeleton undergoes a hydrothermal chemical conversion to hydroxyapatite. The Bio-eye Hydroxyapatite Ocular Implant will now be supplied sterile.

The Interpore 200 Porous Hydroxyapatite is identical to the Motility Orbital Implant described above. Interpore is the manufacturer and supplier of the Motility Orbital Implant. The Interpore 200 Porous Hydroxyapatite is sterilized by gamma radiation and is supplied sterile.

The Ophthalmic Conformer, which is now 510(k) exempt (Federal Register 1-21-98), will now be supplied sterile.

7. **SUMMARY OF PERFORMANCE DATA:** Not applicable.
8. **CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS:** Not applicable.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integrated Orbital Implants, Inc.
Ms. Jeanne Dunham
President
Bioserv Corporation
5340 Eastgate Mall
San Diego, CA 92121

Re: K982562
Trade Name: Bio-eye ® Hydroxyapatite Ocular Implant and Conformer
Regulatory Class: II
Product Code: 86 HPZ
Dated: November 3, 1998
Received: November 5, 1998

Dear Ms. Dunham:

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) 594-4613. 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" (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

510(k) Bio-eye Hydroxyapatite Ocular Implant and Conformer
Integrated Orbital Implants, Inc.
July 1998

No 510(k) Number has been issued

Device Name: Bio-eye® Hydroxyapatite Ocular Implant and Conformer

Indications for Use:

The Bio-eye Hydroxyapatite Ocular Implant is indicated 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 ocular implants are used.

The Conformer is indicated in all cases in which an orbital implant is used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

KYA for DLL
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number _____

Prescription Use

(Per 21 CFR 801.109)

OR

Over-The-Counter
Use _____

(Optional Format 1-2-96)

Prescription Use _____
(Per 21 CFR 801.109)