K060151

AUG - 8 2006

Innovia

510(k) Summary

Submitted By:	Innovia LLC 12415 SW 136 Ave, Unit 3 Miami, FL 33186
Contact Person:	Stewart B. Davis M.D. Assistant Medical Director
Phone Number: **Fax Number:** **Email:**	305-378-2651 Ext. 314 305-378-2652 stewart@innovia-llc.com
Date Prepared:	January 18, 2006
Name of Device:	Orbital Tissue Expander (OTE)
Equivalent Device:	Osmed Hydrogel Tissue Expander from IOP Inc. (K010852)
Intended Use:	The OTE would be used in the case of congenital anophthalmia, congenital microphthalmia or acquired anophthalmia from, e.g., childhood ocular tumors or trauma. It will facilitate normal growth of orbital soft tissues and bone, in efforts to achieve facial symmetry.
Device Description:	The integrated orbital tissue expander (OTE), consisting of a flexible "balloon/expander" is held in place by means of a titanium fixation plate that is anchored to the lateral orbital wall by screws. A slotted arm attached to the fixation plate, extends through a slot that is formed within the OTE. The OTE can be manually moved along the shaft of the fixation plate to achieve optimal central position in an expanding socket. A 30 gauge disposable hypodermic needle connected to a 1 cc disposable syringe filled with sterile saline is inserted into the OTE through an injection port. Inflation of the OTE will effect pressure on the orbit of the patient.
Comparison to Predicate Device:	The OTE is similar to the predicate device in that it can be easily implanted within the orbit, at a small size, and then increased in size to stimulate orbital bony growth. The predicate device grows on its own, by osmosis. The OTE size is user controlled. CT scans can be used to match up sizes with the contralateral eye, and then saline can be injected to enlarge the OTE.

Performance Data: Bench testing has shown that orbital tissue expanders can be fabricated in a repeatable and reliable manner. Both *in vitro* and *in vivo* testing have shown that the tissue expander maintains adequate volume and diameter over time. Fatigue testing has shown durability.

Animal Data: The animal study clearly demonstrated a noticeable difference in sockets expanded with the OTE as compared to the control sockets with anophthalmos. The experimental expanded orbits kept pace with bone growth development on the contralateral non-enucleated side. This qualitative difference can be observed on CT scans as well as in gross photos. The histology performed in all animals showed normal tissues, free of foreign body reaction.

Conclusions: Testing has shown that the OTE can be fabricated in a consistent manner. Animal testing has shown the device to be safe and effective. In-vitro testing has shown the OTE to be durable over time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2006

Innovia, LLC
c/o Stewart B. Davis, M.D.
Assistant Medical Director
12415 SW 136 Avenue
Unit 3
Miami, FL 33186

Re: k060151
Trade/Device Name: Orbital Tissue Expander
Regulation Number: 21 CFR 886.3320
Regulation Name: Eye Sphere Implant
Regulatory Class: Class II
Product Code: NFM
Dated: July 19, 2006
Received: July 25, 2006

Dear Dr. Davis:

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

Indications for Use

510(k) Number (if known): K060151

Device Name: Orbital Tissue Expander

Indications for Use: The OTE would be used in the case of congenital anophthalmia, congenital microphthalmia or acquired anophthalmia from, e.g., childhood ocular tumors or trauma.

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 K060151