MAR 1 5 2006

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K053622

Contact Person: Jason Malecka
President
IOP, Inc.
3184-B Airway Ave.
Costa Mesa, CA 92626
Phone: 714-549-1185
FAX: 714-549-0557

Date Prepared: December 22, 2005

Device Name and Classification

Proprietary Name:	SURGISIS Ocular Graft
Common Name:	Ophthalmic Implant Biologic
Classification Name:	Prosthesis, Eyelid Spacer Graft, Biologic
Classification:	Class II (Exempt from Premarket notification procedures)
Product Code:	NXM
Classification No.:	21 CFR 886.3130

Device Description

The SURGISIS Ocular Graft is derived from porcine small intestinal submucosa (SIS). The material is prepared into sheets of various sizes and thicknesses appropriate for the reconstruction and repair of soft tissues. The device is supplied sterile in a dry lyophilized state sealed in a double peel pouch system

Indications for Use

The Surgisis Ocular Graft is intended for implantation to reinforce and support the reconstruction of the soft tissue of the eyelid.

Summary of Testing

The Surgisis ocular graft is identical in material composition to predicate Surgisis devices and has undergone extensive biocompatibility testing, viral inactivation testing and mechanical testing. Outcomes demonstrate safety and efficacy for soft tissue reconstruction and repair.

Substantial Equivalence Claim

Surgisis Ocular Graft is similar with respect to intended use, materials and technical characteristics to predicate devices.

Predicate Device Equivalence

Company	**Innovative Ophthalmic Products Inc.**	**Cook Biotech Inc.**	**Bio-Tissue, Inc.**
Product Name(s)	SURGISIS Ocular Graft	Surgisis Soft Tissue Graft SIS Plastic Surgery Matrix SIS Facial Implant	ProKera™ Ophthalmic Conformer with Amniotic Membrane
510(k)	Applied For	K980431 K034039 K050246	K032104
Product Specifications			
Material	Processed porcine submucosa	Processed porcine submucosa	Amniotic Membrane with ophthalmic conformer used as an epithelial insert
Indications for Use	General reconstruction of the eyelid. Eyelid Spacer Graft	Implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in face and head and plastic and reconstructive surgery	Intended for use in eyes in which the ocular surface cells have been damaged or underlying stoma is inflamed and scarred. The device in inserted between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions
Supplied	Sterile	Sterile	Unknown
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Unknown
Recommended Usage	Single Use	Single Use	Single Use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

IOP, Inc.
Mr. Jason Malecka, President
3184 Airway Avenue, Bldg. B
Costa Mesa, CA 92626

Re: K053622
Trade/Device Name: Prosthesis, eyelid spacer/graft, biologic
Regulation Number: 21 CFR 886.3130
Regulation Name: Ophthalmic Conformer
Regulatory Class: Class II
Product Code: NXM
Dated: December 22, 2005
Received: December 28, 2005

Dear Mr. Malecka:

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.

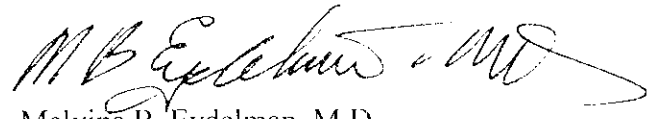
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 827-8910. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Acting Division 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): K053622

Device Name: SURGISIS Ocular Graft

Indications For Use:

The SURGISIS Ocular Graft is intended for implantation to reinforce and aid reconstruction of the eyelid and is labeled for single use.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053622