K971203

Date Prepared: November 7, 1997

FEB - 4 1998

ADMINISTRATIVE INFORMATION

Manufacturer Name: Integrated Orbital Implants, Inc.
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DEVICE NAME

Classification Name: Accessory to Eye Sphere Implant

Trade/Proprietary Name: Perry-Kolberg (PK) Titanium Motility/Support System

Common Name: Ocular motility peg system

ESTABLISHMENT REGISTRATION NUMBER

IOI is registered with FDA under Establishment Registration Number 2027377.

DEVICE CLASSIFICATION

Ocular motility peg or screw systems have not been classified by FDA. They are used as accessories to Eye Sphere Implants, shown in 21CFR 886.3320 and recommended in FR 47 page 3725, January 26, 1982, as Class II devices. Therefore, they are reviewed as Class II devices. A new Product Code recently assigned to one of the predicate devices, the MEDPOR Ocular Screw (K971583) is MQU.

The PK Titanium Threaded Sleeve Wrench and PK Titanium Needle Drill Handles used with the PK Titanium Motility/Support System are manual ophthalmic surgical instruments

(21 CFR 886.4350), Class I devices that are exempt from premarket notification. They are included in this submission only for reference and to explain the use of the PK Titanium Motility/Support System.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the PK Titanium Motility/Support System complies include American Society for Testing and Materials (ASTM) designation F-136, "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications," and American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Process Control Guidelines for Gamma Radiation Sterilization (ANSI/AAMI ST32-1991).

PACKAGING/LABELING/PRODUCT INFORMATION

Product labeling and advertising material to be used for promotion of the PK Titanium Motility/Support System will be consistent with the indications for use and other material shown herein.

The PK Titanium Motility/Support System will be packaged in a radiation sterilizable, disposable pouch or tray. Product will be provided either non-sterile or sterile (appropriately labeled). Sterilization will be accomplished by means of Co^{60} gamma irradiation at a dose of 25 kG (2.5 Mrad) minimum. Sterilization will be validated by the bioburden method, using American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Process Control Guidelines for Gamma Radiation Sterilization (ANSI/AAMI ST32-1991). The sterility assurance level (SAL) that IOI intends to meet for the sterile version of the PK Titanium Motility/Support System is 10^{-6}. The device is not represented to be "pyrogen free."

INTENDED USE

The Perry-Kolberg Titanium Motility/Support System is intended to provide a direct mechanical coupling of an ocular prosthesis to an orbital implant (eye sphere implant) in order to enhance motility of the prosthesis over that of a prosthesis used without a direct coupling to the implant. It also reduces the weight of the ocular prosthesis on the lower eyelid. It may be placed in a secondary operation that occurs after the ocular implant has become vascularized, approximately three to six months after implant placement. Alternatively, it may be placed during the initial implantation procedure before closing the Tenon's capsule and the conjunctiva.

DEVICE DESCRIPTION

Design Characteristics

The Perry-Kolberg (PK) Titanium Motility/Support System consists of the PK Titanium Threaded Sleeve, the PK Titanium Flat Peg for Sleeve, the PK Titanium Locking Socket Peg for Sleeve, the PK Titanium Motility Ball Peg for Sleeve, the PK Titanium Threaded Sleeve Wrench and a series of PK Titanium Needle Drill Handles. The latter two devices are Class I, exempt devices, and are included in this submission only for reference and to explain the use of the PK Titanium Motility/Support System. The Threaded Sleeve is an externally threaded cylinder with an internal drilled hole designed to receive a peg. It is placed in the Bioeye® Hydroxyapatite Implant with the use of the PK Titanium Threaded Sleeve Wrench after a hole is prepared in the implant by drilling with a series of hypodermic needles of gradually increasing size, from 21-gauge to 14 gauge. The needles are held with the PK Titanium Needle Drill Handle.

After the Threaded Sleeve is placed in the implant, any of the PK Motility Pegs can be inserted. The PK Titanium Flat Peg for Sleeve can be used as a temporary device to maintain the integrity of the drilling hole or can, in some cases, be used to directly attach to the ocular prosthesis. The PK Titanium Locking Socket Peg for Sleeve is designed to aid in retention of a prosthesis even in extreme gazes by locking into the ocular prosthesis and avoiding the loss of engagement of the peg and the motility hole. It is manufactured with a shaft length that is adjustable in one millimeter increments by the ocularist, to meet each patient's individual requirements. A non-adjustable ball and socket peg, the PK Titanium Motility Ball Peg for Sleeve, is also included in the system.

Material Composition

All of the components of the PK Titanium Motility/Support System are made from titanium-aluminum-vanadium conforming to ASTM Specification F136. Titanium and titanium-aluminum-vanadium alloy are well-recognized for their biocompatibility and are used as negative controls in many biocompatibility tests.

EQUIVALENCE TO MARKETED PRODUCT

IOI submits the following information to demonstrate that the Perry-Kolberg Titanium Motility/Support System shares indications and design principles with the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: MEDPOR Ocular Screw and Accessories (K971583), MEDPOR Ocular Peg System and Accessories (K960859), MEDPOR Ocular Screw and Accessories (K954939).

Intended Use

The indications for use of the PK Titanium Motility/Support System are not new indications in that they are the same as or are included in those for the predicate devices. All are intended to provide a direct mechanical coupling of an ocular prosthesis to an orbital implant (eye sphere implant) in order to enhance motility of the prosthesis over that of a prosthesis used without a direct coupling to the implant.

Design and Materials

The design and functional characteristics of the PK Titanium Motility/Support System and the predicate devices are similar. All are simple threaded cylindrical devices that are designed to be inserted into an orbital implant and to engage an ocular prosthesis by means of a head or peg. This provides the ocular prosthesis with improved motility over that of a prosthesis that is not coupled to the orbital implant. The MEDPOR predicate devices are available in both high density polyethylene (HDPE) and in titanium alloy, the material of the subject device. The subject device and the predicate devices are accompanied by instruments for threading or inserting the screw or peg into the ocular prosthesis. The subject device and the MEDPOR Ocular Screw are designed for either primary or delayed placement in the orbital implant.

The lay distinctions between the devices are that the PK Titanium Motility/Support System and the MEDPOR Ocular Peg System (K960859) are both two-piece systems consisting of an outer threaded sleeve that is inserted into the ocular implant and a peg that is inserted into the outer sleeve, while the MEDPOR Ocular Screw (K971583, K954939) is a one-piece device that must be inserted into the ocular implant with the head protruding exactly as it will be used by the ocularist. No adjustment is possible, without further surgical treatment, after the screw is placed.

The PK Titanium Motility/Support System combines the principles of operation of the two-piece MEDPOR Ocular Peg System with the titanium alloy composition of the MEDPOR Ocular Screw. The degree of protrusion of the head of the PK Titanium Motility/Support System can be adjusted by use of the PK Titanium Locking Socket Peg for Sleeve, which is notched to allow for the removal of the appropriate length of its shaft before insertion. Pegs of the MEDPOR Ocular Screw can be adjusted for length by cutting off the necessary portion of the shaft.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Perry-Kolberg Titanium Motility/Support System is substantially equivalent to the MEDPOR Ocular Screw and Accessories (K971583, K954939) and the MEDPOR Ocular Peg System and Accessories (K960859) in the following respects:

	Subject Device	Predicate Devices	
	Perry-Kolberg Titanium Motility/Support System	MEDPOR Ocular Screw and Accessories (K971583, K954939)	MEDPOR Ocular Peg System and Accessories (K960859)
INTENDED USE	To provide a direct mechanical coupling of an ocular prosthesis to an orbital implant (eye sphere implant) in order to enhance motility of the prosthesis over that of a prosthesis used without a direct coupling to the implant. It also reduces the weight of the ocular prosthesis on the lower eyelid. It may be placed in a secondary operation that occurs after the ocular implant has become vascularized or in a primary operation at the time of placement of the orbital implant	The MCP® (Motility Coupling Post) is indicated for patients with MEDPOR Ocular Implants, who desire improved prosthetic eye motility via direct coupling of the implant to the prosthetic eye. Primary placement . . . may occur during the initial reconstruction procedure, following attachment of the extraocular muscles to the ocular implant but before closing of the Tenon's capsule and the conjunctiva layer. Secondary placement may occur typically 3-6 months post enucleation after the ocular implant has become vascularized.	The MEDPOR Ocular Peg is indicated for patients with MEDPOR Ocular Implants, who desire improved prosthetic eye motility via direct coupling of the implant to the prosthetic eye. It is intended for secondary placement, typically 3-6 months post enucleation after the ocular implant has become vascularized.

TABLE OF SUBSTANTIAL EQUIVALENCE, continued.

	Subject Device	Predicate Devices	
	Perry-Kolberg Titanium Motility/Support System	MEDPOR Ocular Screw and Accessories (K971583, K954939)	MEDPOR Ocular Peg System and Accessories (K960859)
DESIGN	Two-piece threaded screw and post system that is inserted into an ocular implant to improve motility of an ocular prosthesis. Screw is inserted into the implant and peg is placed in the internal hole in the screw. Head of peg couples with a socket formed in the posterior surface of the ocular prosthesis	One-piece threaded screw/post that is inserted into an ocular implant to improve motility of an ocular prosthesis. Head height is varied by varying depth of placement of the screw in the implant. Head couples with a socket formed in the posterior surface of the ocular prosthesis.	Two-piece threaded screw and post system that is inserted into an ocular implant to improve motility of an ocular prosthesis. Screw is inserted into the implant and peg is placed in the internal hole in the screw. Head of peg couples with a socket formed in the posterior surface of the ocular prosthesis
MATERIAL	Titanium-6Al-4V alloy	Titanium-6Al-4V alloy	High density polyethylene (HDPE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 1998

Integrated Orbital Implants, Inc.
c/o Mr. Floyd G. Larson
Pacific Materials and Interfaces
4329 Graydon Road
San Diego, CA 92130

Re: K974203
Trade Name: Perry-Kolberg (PK) Titanium Motility/Support System
Regulatory Class: II
Product Code: 86 MQV
Dated: November 7, 1997
Received: November 10, 1997

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) 594-4613. 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

Indications for Use Statement

510(k) Number: K974203

Device Name: Perry-Kolberg Titanium Motility/Support System

Indications for Use:

The Perry-Kolberg Titanium Motility/Support System is intended to provide a direct mechanical coupling of an ocular prosthesis to an orbital implant (eye sphere implant) in order to enhance motility of the prosthesis over that of a prosthesis used without a direct coupling to the implant. It also reduces the weight of the ocular prosthesis on the lower eyelid. It may be placed in a secondary operation that occurs after the ocular implant has become vascularized, approximately three to six months after implant placement. Alternatively, it may be placed during the initial implantation procedure before closing the Tenon's capsule and the conjunctiva.

Donna R. Vechner.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K974203

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____