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510(k) SUMMARY

Manufacturer and Submitter

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Trade Name MEDPOR® Ocular Peg System and Accessories
Classification Name: Device is not classified

Substantially equivalent to:
A: The ocular pegging system offered in conjunction with the porous hydroxyapatite sphere implant distributed by Integrated Orbita Implants

B: The MEDPOR® Ocular Screw and Accessories

Device description:

The MEDPOR® Ocular Peg and Sleeve and Accessories consist of two HDPE (High Density Polyethylene) Pegs, and an HDPE Sleeve with the necessary associated manual surgical instruments. The pegs and sleeve will be sold as a package, supplied sterile. All other components will be supplied separately, non-sterile.

The associated surgical instruments include an Ocular Implant Clamp for holding the implant during the procedure, a sleeve driver for screwing the sleeve into the implant, and three drill bits for drilling the hole for the peg or peg and sleeve. The ocular implant clamp, sleeve driver and drill bit(s) are each a manual ophthalmic surgical instrument as defined by 21 CFR 886.4350, and as such are exempt from premarket notification procedures. They are presented here with brief descriptions so that a complete understanding of the device (the pegs and sleeve), and its use, will be provided.

Ocular Pegs

The pegs are intended for single patient use. The pegs are composed of HDPE (High Density Polyethylene), identical to the HDPE used to manufacture the MEDPOR® Implant. Two peg styles will be available; a flat head peg for use immediately after the hole is drilled until the prosthetic eye is modified to accept the round head peg, and the round head peg. The shank diameter in both pegs is 1.8mm. The domed head is 2.5mm in diameter. The domed head of the peg is designed to fit in a socket made in the back of a custom ocular prosthesis. The ocular prosthesis is an external custom device made by a professional ocularist.

The ocular pegs are supplied sterile. They are sterilized by contract sterilizer in Ethylene Oxide gas. Sterilizer cycles have been validated, and are periodically re-validated, according to AMMI accepted practices and guidelines. Product is released based on bio-indicator assurance that a sterility assurance level of 10 to the minus 6 power has been achieved.

Sleeve

The sleeve is manufactured of the same HDPE (High Density Polyethylene). The sleeve is designed to mate with the shaft of the peg. The sleeve is supplied sterile and is intended for single patient use. They are sterilized by contract sterilizer in Ethylene Oxide gas. Sterilizer cycles have been validated, and are periodically re-validated, according to AMMI accepted practices and guidelines. Product is released based on bio-indicator assurance that a sterility assurance level of 10 to the minus 6 power has been achieved.

Sleeve Driver

The sleeve driver is a manual instrument for screwing the sleeve into the hole drilled into the MEDPOR implant. The sleeve driver is 316 stainless steel, and will be sold non-sterile.

Drill Bits

The drill bits are surgical stainless steel, twist drill bits to be used for drilling the holes for the peg or sleeve. Three drill bits will be available. A 1.2mm drill bit for drilling a pilot hole, a 2.3mm drill bit for drilling the hole for the peg without the sleeve, and a 3.1mm bit for drilling the hole for the sleeve. The drill bits are supplied non-sterile, and are intended to be re-usable.

Ocular Clamp

The ocular clamps are manufactured of surgical stainless steel and are intended to be re-usable. The ocular clamp is used to hold the ocular eye sphere implant immobile during the drilling of the hole for the peg or sleeve. Two sizes will be available, a pediatric and an adult size. The ocular clamps are supplied non-sterile, and are intended to be re-usable. Although these are hand held ophthalmic instruments and thus do not require 510(k) approval they are included here for explanatory purposes.

STERILIZATION

The MEDPOR® Ocular Pegs and Sleeve are provided STERILE. Resterilization is not recommended.

The Drill Bits, Sleeve Driver and Implant Clamps must be sterilized prior to use. Based on AAMI and current JCAHO standards, the Drill Bits, Sleeve Driver, and Clamps should be wrapped and sterilized using moist heat and a vacuum cycle, using the institution's sterilization policy or by the following guidelines:

Vacuum sterilize at 275 degrees F, for minimum 15 minutes, and dry for 15 minutes. An appropriate chemical process indicator should be included with the implant to assure sterility.

Flash sterilization (gravity cycle) is not recommended for routine sterilization.

Biocompatibility

The Ocular Pegs and Sleeve are made from the same grade HDPE as the MEDPOR® Ocular Implants, in molds made from the same materials, using the same heat and pressure process used to make the Barrier portion of the MEDPOR® Barrier Implants. Biocompatibility of this material is well established by over ten years of animal and human clinical studies before FDA approval to market MEDPOR® Biomaterial in 1985, and over 10 years of clinical experience since then.

There are no changes in the method of sterilization, the sterilization assurance level, material of construction, quality control procedures, or packaging.

Background for Product Use

After routine enucleation or evisceration of the eye by an ophthalmologist or oculoplastic surgeon, the void is filled with a MEDPOR® Surgical Implant in the form of a sphere or in the form of a conical shape . The muscles of the eye are routinely attached to the implant or a tissue covering to provide motility to the implant after healing has taken place. The surgeon then closes the Tenon's capsule and conjunctiva around the anterior portion of the implant.

After the conjunctiva covering the implant heals and the swelling subsides, the surgeon refers the patient to an ocularist for fitting of a custom external eye prosthesis. The ocularist creates an artfully designed prosthetic eye. The prosthetic eye is made, for example, of a plastic such as polymethylmethacrylate (PMMA) and decorated to match the contra lateral real eye. The prosthesis is then worn by the patient between the healed eye globe and eye lids in a manner similar to a contact lens.

Many ophthalmologists and oculoplastic surgeons feel that simply inserting the prosthetic eye over the tissues covering the implant provides adequate motility and cosmesis. Others, however, believe enhanced motility can be achieved by a direct coupling of the orbital implant to the external prosthesis. This mechanical coupling is provided by drilling a hole in the anterior surface of the implant, and placing a peg in the hole. The domed head of the peg fits into a matching socket provided in the back of the prosthesis.

Comparison With Predicate Devices

A porous hydroxyapatite implant currently marketed by Integrated Orbital Implants (IOI) utilizes an acrylic peg placed into a drilled hole in the implant, or into a solid sleeve threaded into a drilled hole as a coupling device. The use of the MEDPOR® Ocular Peg System performs the same function as the acrylic peg, the only difference being that it is manufactured from High Density Polyethylene.

The MEDPOR® Ocular Screw, currently approved for marketing by the FDA, couples the MEDPOR® Ocular Implant to the prosthesis via the head of a titanium screw placed into a hole drilled into a well vascularized implant. The MEDPOR® Ocular Peg System performs the same function as the Medpor® Ocular Screw, the only difference being that an HDPE Peg, or Sleeve and Peg, is used in the place of the screw.