



Food and Drug Administration  
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December 17, 2015

Innovative Ophthalmic Products, Inc. (iop)  
% Mr. James Ravitz  
Partner  
Arent Fox, LLP  
1717 K Street, NW  
Washington, DC 20006

Re: K152996  
Trade/Device Name: Molteno3 Glaucoma Implant  
Regulation Number: 21 CFR 886.3920  
Regulation Name: Aqueous Shunt  
Regulatory Class: Class II  
Product Code: KYF  
Dated: October 12, 2015  
Received: October 14, 2015

Dear Mr. Ravitz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Kesia Y. Alexander -A

for 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): New Submission

Device Name: Molteno3 S-Series Glaucoma Implant

**Indications For Use:**

The Molteno3 S-Series Glaucoma Implant is intended to reduce intraocular pressure in neovascular glaucoma and glaucoma where medical and conventional surgical treatments have not been successful to control the progression of disease.

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)

## **510(K) SUMMARY**

### **I. SUBMITTER**

Innovative Ophthalmic Products, Inc. (IOP, Inc.)  
3184-B Airway Avenue  
Costa Mesa, CA 92626

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Date Prepared: November 13, 2015

### **II. DEVICE**

Name of Device: Molteno3 S-Series  
Common or Usual Name: Glaucoma Implant  
Classification Name: Aqueous Shunt (21 CFR 886.3920)  
Regulatory Class: II  
Product Code: KYF

### **III. PREDICATE DEVICE**

Molteno3 G-Series Implant (K062252).  
This predicate has not been subject to a design-related recall.  
No reference devices were used in this submission.

### **IV. DEVICE DESCRIPTION**

The Molteno3 S-Series Glaucoma Implant comes in two sizes and consists of a fine bore, flexible silicone translimbal tube attached to the upper surface of an injection molded polypropylene episcleral plate with a surface area of either 185mm<sup>2</sup> (size: SS) or 245mm<sup>2</sup> (size: SL). The function of the translimbal tube is to deliver aqueous humor (“aqueous”) from within the anterior chamber of the eye onto the upper surface of the episcleral plate. The function of the plate is, when the device is implanted below the Tenon’s capsule, to initiate the formation of a large circular bleb which develops a specialized fibrovascular bleb lining and becomes distended by aqueous fluid.

The Molteno3 devices have an oval pressure ridge on the upper surface of the episcleral plate that divides the upper surface of the plate into a small, primary and a large, secondary drainage chamber. The S-Series device has a lower ridge profile and the two front suture holes have been moved to a more anterior position than the predicate G-Series device.

The Molteno3 implants may be inserted between the sclera and the Tenon’s tissue, so that the device would lie below both the Tenon’s tissue and the overlying conjunctiva. However, other surgical techniques may be employed during the placement of a Molteno Implant, consistent with the surgeon’s judgment.

The device is intended for single use, is packaged individually in polypropylene presentation boxes, and is sold sterile.

## V. INDICATIONS FOR USE

The Molteno3 S-Series glaucoma implant is intended to reduce intraocular pressure in neovascular glaucoma or glaucoma where medical and conventional surgical treatments have not been successful to control the progression of disease.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Molteno3 G-Series (K062252)	Molteno3 S-Series
<b>Indication for Use</b>	The Molteno3 G-Series Glaucoma Implant is intended to reduce intraocular pressure in neovascular glaucoma and glaucoma where medical and conventional surgical treatments have not been successful to control the progression of disease.	The Molteno3 S-Series Glaucoma Implant is intended to reduce intraocular pressure in neovascular glaucoma and glaucoma where medical and conventional surgical treatments have not been successful to control the progression of disease.
<b>Materials/Composition</b>	Polypropylene episcleral plate attached to silicone drainage tube using silicone adhesive. No color additives used – all components are colorless.	Polypropylene episcleral plate attached to silicone drainage tube using silicone adhesive. No color additives used – all components are colorless.
<b>Surface Area of Plate</b>	GS = 175mm <sup>2</sup> single plate GL = 230mm <sup>2</sup> single plate	SS = 185mm <sup>2</sup> single plate SL = 245mm <sup>2</sup> single plate
<b>Plate Thickness</b>	0.4mm	0.4mm
<b>Ridge Height above Lower Surface of Plate</b>	1.15mm	0.95mm
<b>Maximum Plate Length</b>	GS = 14.2mm GL = 16.0mm	SS = 15.4mm SL = 17.4mm
<b>Maximum Plate Width</b>	GS = 13.6mm GL = 15mm	SS = 13.6mm SL = 15mm
<b>Tubing</b>	Internal diameter: 0.34mm External diameter: 0.64mm	Internal diameter: 0.34mm External diameter: 0.64mm
<b>Translimbal Tube Length</b>	GS = 19mm GL = 17mm	SS = 19mm SL = 17mm
<b>Sterilization Method</b>	Steam Autoclave ISO 17665:1	Steam Autoclave ISO 17665:1
<b>Recommended Usage</b>	Single Use	Single Use
<b>How Supplied</b>	Sterile	Sterile
<b>Shelf Life</b>	5 years from sterilization	5 years from sterilization
<b>Packaging</b>	Polypropylene Presentation Box	Polypropylene Presentation Box

The S-Series device differs from the predicate G-Series device only in that the S-Series device has a lower ridge profile and the two front suture holes have been moved to a more anterior position. As a result of these changes, the overall plate length has increased very slightly.

## **VII. PERFORMANCE DATA**

### **A. Bench Testing**

As described in the substantial equivalence comparison chart above, the materials used for the Molteno3 S-Series implant are identical to the FDA-cleared device. Moreover, the design of the devices is virtually identical and the devices are produced by the identical manufacturing process. Accordingly, the bench testing described in FDA's 1998 guidance document entitled "Aqueous Shunts – 510(k) Submissions" and the associated ANSI Standard Z80.27 "for Ophthalmics – Implantable Glaucoma Devices" was deemed to be unnecessary. Although sterilization procedures have also not changed, bacterial endotoxin testing was nevertheless carried out at a US testing facility and confirmed that the devices are in conformity with FDA's recommended limit of  $\leq 0.2$  EU/device.

### **B. Clinical Evidence Supporting Substantial Equivalence**

Clinical data developed using both the G-Series and S-Series implants support the conclusion that the performance of the S-Series implant is equivalent to that of the G-Series. More specifically, clinical data from the use of the Molteno3 S-Series device in the United States were compared to published historical data from the Otago Glaucoma Surgery Outcome study and a similar Finnish study, along with additional unpublished data from the Otago study. Clinical performance of the aqueous shunt under investigation was compared to appropriate historical populations, and the analysis included data from 70 patients receiving the S-Series implant followed out for at least one year. Outcome data for IOP and post-operative reduction in medications, as well as visual acuity, were evaluated, along with data on relevant adverse events. The comparison established that there is no clinically significant difference in outcome between the devices, confirming that the Molteno3 S-Series implant is as safe and effective as the predicate Molteno3 G-Series implant.

## **VIII. CONCLUSIONS**

In summary, the Molteno3 S-Series implant and the G-Series implant are manufactured from the same materials and according to the same manufacturing process, are packaged and labeled identically, and have the same Indication for Use and the same technological characteristics. Clinical data establish that the S-Series device is as safe and effective as the predicate G-Series device. The information presented in this submission thus establishes that the Molteno3 S-Series implant is substantially equivalent to the Molteno3 G-Series implant.