DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 24, 2016

New World Medical, Inc.
Mr. Suhail Abdullah
Chief Scientific Officer
10763 Edison Court
Rancho Cucamonga, CA 91730

Re: K162060
Trade/Device Name: Ahmed Glaucoma Valve
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous Shunt
Regulatory Class: Class II
Product Code: KYF
Dated: July 25, 2016
Received: July 26, 2016

Dear Mr. Abdullah:

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 Alexander

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ahmed Glaucoma Valve Model FP7

Indications for Use *(Describe)*
The Ahmed Glaucoma Valve is indicated for the management of refractory glaucomas, where previous surgical treatment has failed, or by experience is known not to provide satisfactory results. Such refractory glaucomas can include neovascular glaucoma, primary open angle glaucoma unresponsive to medications, congenital or infantile glaucoma, and refractory glaucomas resulting from aphakia or uveitis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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This 510(k) Summary has been prepared in accordance with 21CFR807.92

Date Prepared and Submitted:

July 25th, 2016

Address and Registration

Submitter: New World Medical, Inc.

The address and registration number of the manufacturer and sterilization site of all Ahmed™ Glaucoma Valve Models are:

Manufacturer	Sterilization Site
New World Medical, Inc. 10763 Edison Court Rancho Cucamonga, CA 91730 Phone: 909-466-4304 Fax: 909-466-4305 Contact Person: Suhail Abdullah **FDA REGISTRATION #: 1000125279**	Sterigenics U.S., LLC 344 Bonnie Circle Corona, CA 92880 **FDA REGISTRATION #: 2029275**

Device Name

The device trade name and common/classification name are:

Device Trade Name	Common Name	Classification Name
Ahmed™ Glaucoma Valve Implant Model FP7	Glaucoma Drainage Device	Aqueous Shunt (21 CFR 886.3920, Product Code KYF)

Predicate Device

The two predicate devices are the **Ahmed™ Glaucoma Valve Model S2** which was first marketed in 1993 and the **Baerveldt Glaucoma Implant**, first marketed in 1991. The Ahmed™ Glaucoma Valve Model FP7 is a modification to the Ahmed™ Glaucoma Valve Model S2 (510(k) Number: **K925636**) in which the plate design and material have been modified.

Predicate devices information
510(k) Number: **K925636**
Device Name: **Ahmed™ Glaucoma Valve Model S2**
Decision Date: **11/12/1993**

510(k) Number: **K905129**
Device Name: **Baerveldt Glaucoma Implant**
Decision Date: **02/11/1991**

Device Class

Ahmed™ Glaucoma Valve Implants have been classified as Class II in the Ophthalmic panel (21CFR886.3920) with product code KYF.

Intended Use

The Ahmed™ Glaucoma Valve is intended for use in the surgical management of refractory glaucomas, where previous surgical treatment has failed, or by experience is known not to provide satisfactory results. Such refractory glaucomas can include neovascular glaucoma, primary open angle glaucoma unresponsive to medications, congenital or infantile glaucoma, and refractory glaucomas resulting from aphakia or uveitis.

This is the same intended use as the previously cleared Ahmed™ Glaucoma Valve S2, 510(k) Number K925636

Device Description and Technological Characteristics

The Ahmed™ Glaucoma Valve Model FP7 (AGV-FP7) is a valved aqueous drainage implant designed to regulate intraocular pressure in eyes suffering from intractable glaucoma. The Ahmed™ device is comprised of a silicone drainage tube that is connected to a valve mechanism. This valve mechanism is the same in the AGV-FP7 and the predicate AGV-S2. The valve mechanism consists of a silicone sheet folded and pressed between two complimentary polypropylene plates. The valve mechanism is securely positioned in a pocket inside of a silicone endplate that serves to distribute the aqueous humor from the anterior chamber of the eye over the surface of the endplate. The valve in the AGV-FP7 behaves like a variable resistor, decreasing resistance to allow more flow when intraocular pressure is high. When pressure is low, the resistance to fluid outflow is high and the valve closes, thereby preventing hypotony. By means of the valve mechanism, the AGV-FP7 maintains intraocular pressure within the appropriate physiological range.

In both the AGV-S2 and AGV-FP7, the silicone sheet is folded and pressed between two polypropylene plates. In the AGV-S2, the bottom polypropylene plate is comprised of the polypropylene endplate body. In the AGV-FP7, the polypropylene bottom plate is separate from the silicone endplate material. The valve mechanism is inserted into a pocket in the silicone endplate to fixate the valve components to the endplate. Additional differences include stiffening ribs in the posterior half of the AGV-FP7 to add stiffness to the flexible endplate, The other predicate device, the Baerveldt Glaucoma Implant (BGI) also consists of a flexible silicone endplate which shares some features with the AGV-FP7, though the BGI endplate is larger in area. The AGV-FP7 endplate has the same curvature as the average human eye at its equator and also protects the valve from blockage by fibrous tissue. The endplate is made of flexible silicone. Inflammation and scarring around flexible silicone implants in animal ocular tissue was less pronounced than that found around rigid polypropylene.

Testing

Extensive non-clinical testing of the AGV-FP7 has been performed per the FDA Guidance on Aqueous Shunts and includes the following:

- Physical Stability testing to ensure that the device maintains its performance characteristic and structural integrity after exposure to an aqueous environment at body temperature.
- Chemical analysis and aqueous aging chemical testing to assess any potential chemical hazards and stability of device materials
- Validation of the packaging system
- Sterilization validation
- Distribution simulation and subsequent validation of the stability of the packaging system and device
- Accelerated aging and subsequent validation of the stability of the packaging system and device
- Biocompatibility testing

A published animal study also indicated that the AGV-FP7 valve mechanism is functional in-vivo, as expected, and that the Foreign Body Reaction to the AGV-FP7 is consistent with bleb formation around predicate implant materials such as silicone and polypropylene.

Furthermore, there are several published clinical studies comparing the AGV-FP7 to the predicate AGV-S2 and the BGI. In these studies, the AGV-FP7 group of patients had similar IOP and complication rates to the predicate devices. Particularly, compared to the AGV-S2, the IOP of the AGV-FP7 groups was lower (within the acceptable physiological range) and fewer complications were reported. This clinical data which includes safety and effectiveness data and information on adverse effects and complications associated with the AGV-FP7 can be found in the referenced citations below.

1. The Ahmed Baerveldt Comparison Study. This study compared the long-term outcomes and complication of the Ahmed Glaucoma Valve model FP7 (AGV-FP7) and the Baerveldt glaucoma implant. This was a multicenter, prospective, randomized, controlled clinical trial with several relevant publications which have been cited here.

   Barton K, Gedde SJ, Budenz DL, Feuer WJ, Schiffman J. The Ahmed Baerveldt Comparison Study methodology, baseline patient characteristics, and intraoperative complications. Ophthalmology. 2011 Mar;118(3):435-42. PubMed PMID: 20932581; NIHMSID: NIHMS233027; PubMed Central PMCID: PMC3020244.

   Budenz DL, Barton K, Feuer WJ, Schiffman J, Costa VP, et al. Treatment outcomes in the Ahmed Baerveldt Comparison Study after 1 year of follow-up. Ophthalmology. 2011 Mar;118(3):443-52. PubMed PMID: 20932583; NIHMSID: NIHMS233028; PubMed Central PMCID: PMC3020266.

   Budenz DL, Barton K, Gedde SJ, Feuer WJ, Schiffman J, et al. Five-year treatment outcomes in the Ahmed Baerveldt comparison study. Ophthalmology. 2015 Feb;122(2):308-16. PubMed PMID: 25439606; NIHMSID: NIHMS625185; PubMed Central PMCID: PMC4306613.

   Budenz DL, Feuer WJ, Barton K, Schiffman J, Costa VP, et al. Postoperative Complications in the Ahmed Baerveldt Comparison Study During Five Years of Follow-up. Am J Ophthalmol. 2016 Mar;163:75-82.e3. PubMed PMID: 26596400; NIHMSID: NIHMS746915; PubMed Central PMCID: PMC4901387.

2. Comparison of Polypropylene and Silicone Ahmed Glaucoma Valves. This study was conducted to evaluate and compare clinical outcomes after implantation of the silicone plate Ahmed

Glaucoma Valve Model FP7 (AGV-FP7) and the polypropylene plate Ahmed Glaucoma Valve Model S2 (AGV-S2). This was a prospective, multicenter, comparative study.

Ishida K, Netland PA, Costa VP, Shiroma L, Khan B, et al. Comparison of polypropylene and silicone Ahmed Glaucoma Valves. Ophthalmology. 2006 Aug;113(8):1320-6. PubMed PMID: 16877071.

3. Comparison of silicone and polypropylene Ahmed glaucoma valves: two-year follow-up. The purpose of this study was to compare the safety and efficacy of the silicone Ahmed glaucoma drainage device (AGV-FP7) and the polypropylene Ahmed glaucoma drainage device (AGV-S2). This study was a single surgeon, retrospective, consecutive case series.

   Mackenzie PJ, Schertzer RM, Isbister CM. Comparison of silicone and polypropylene Ahmed glaucoma valves: two-year follow-up. Can J Ophthalmol. 2007 Apr;42(2):227-32. PubMed PMID: 17392844.

Substantial Equivalence

The change from a rigid plate material (AGV-S2) to a softer plate material in the AGV-FP7 does not raise new questions of safety and efficacy. There is no change in intended use and clinical studies have shown similar efficacy and safety profiles compared predicate devices. In summary, the Ahmed™ Glaucoma Valve Model FP7 described in this submission is substantially equivalent to the predicate devices.