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

August 8, 2017

New World Medical, Inc.
Cristina Avalos
Director of Regulatory Affairs
10763 Edison Court
Rancho Cucamonga, CA 91730

Re: K171451
Trade/Device Name: Ahmed Glaucoma Valve Model FP8
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous Shunt
Regulatory Class: Class II
Product Code: KYF
Dated: May 15, 2017
Received: May 17, 2017

Dear Cristina Avalos:

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,

Denise L. Hampton -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171451

Device Name
AGV-FP8

Indications for Use *(Describe)*
The Ahmed® Glaucoma Valve Model FP8 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 medication, 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.

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K171451

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
This 510(k) Summary has been prepared in accordance with 21CFR807.92

o Date Prepared and Submitted:

June 13, 2017

o 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: Cristina Avalos **FDA REGISTRATION #: 1000125279**	Sterigenics U.S., LLC 344 Bonnie Circle Corona, CA 92880 **FDA REGISTRATION #: 2029275**

o Device Name

The device trade name and common/classification name are:

Device Trade Name	Common Name	Classification Name
Ahmed® Glaucoma Valve Implant Model FP8	Glaucoma Drainage Device	Aqueous Shunt (21 CFR 886.3920, Product Code KYF)

o Predicate Device

The two predicate devices are the **Ahmed® Glaucoma Valve Model FP7 (K162060) and the Ahmed® Glaucoma Valve Model S3 (K980657)**. The Ahmed® Glaucoma Valve Model FP8 is a modification to the size of the predicate Model FP7.

Predicate devices information
510(k) Number: **K162060**
Device Name: **Ahmed® Glaucoma Valve Model FP7**
Decision Date: **10/24/2016**

Predicate devices information
510(k) Number: **K980657**
Device Name: **Ahmed® Glaucoma Valve Model S3**
Decision Date: **4/20/1998**

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

o Device Class

Ahmed® Glaucoma Valve Implants have been classified as Class II in the Ophthalmic panel (21CFR 886.3920) with product code KYF.

o Intended Use

The Ahmed® Glaucoma Valve Model FP8 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 medication, 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 FP7, 510(k) Number K162060 and the Ahmed® Glaucoma Valve S3, 510(k) Number K980657

o Device Description and Technological Characteristics

The Ahmed® Glaucoma Valve Model FP8 (AGV-FP8) 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 predicate AGV-FP7. 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-FP8 and the predicate 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-FP8 and the predicate AGV-FP7 maintain intraocular pressure within the appropriate physiological range.

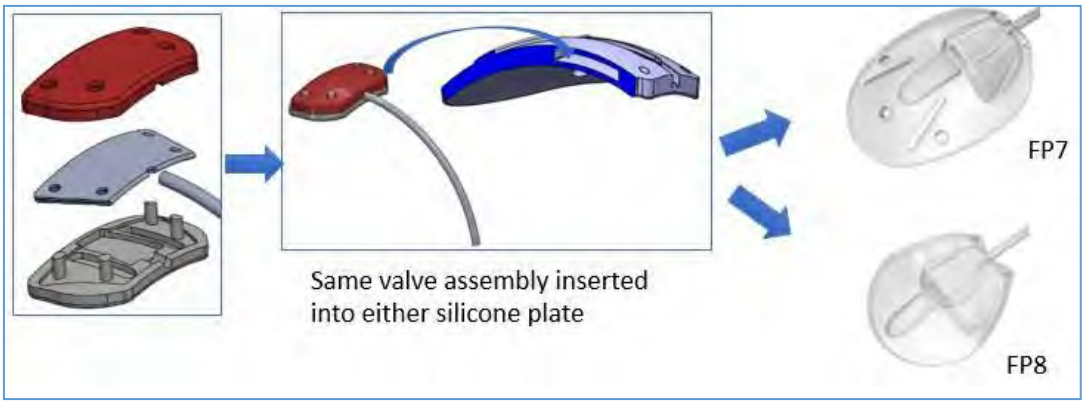
In both the AGV-FP7 and AGV-FP8, the silicone sheet is folded and pressed between two polypropylene plates. The valve mechanism is inserted into a pocket in the silicone endplate to fixate the valve components to the endplate. Differences include stiffening ribs in the posterior half of the AGV-FP7 to add stiffness to the flexible endplate, the AGV-FP7 has a larger surface area and fenestration holes. The AGV-FP8 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.

o Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices are based on the following same technological elements:

- The AGV FP7 and FP8 utilize the same identical valve mechanism which determines the pressure/ flow characteristics of the device. The active valve mechanism, which is comprised of the valve sheet, top/ bottom plate, silicone tube,

and silicone adhesive, are identical for both the AGV FP7 and FP8 in terms of raw materials, components, assembly, and performance criteria.



Assembly of both the AGV FP7 and FP8 valves. The valve units are identical.

- The silicone plate determines the surface area for the device. The plates for both the FP7 and FP8 have identical materials, manufacturing process (including molding equipment, parameters, cleaning, inspection, and packaging/ sterilization), and surface/ edge finish. Though the FP8 silicone plate is smaller than the FP7 plate (102 mm^2 vs 184 mm^2), it is larger than the current S3 (85 mm^2). All three devices (FP7/ FP8/ S3) have the same base curvature.

- The plates for both the FP7 and FP8 are identical with the exception to the surface area and the FP7 having stiffening ribs (to add slight rigidity to the extra silicone surface area). Both utilize the same silicone material and identical processes, including assembly, cleaning, inspection, and packaging/ sterility.

The following technological differences exist between the subject and predicate devices:

- The FP7 and FP8 use the same material and processes for forming the silicone plate. The FP7 has stiffening ribs on the posterior portion to add structural integrity due to having more surface area than the FP8. These ribs do not affect the valve performance.

- The AGV FP7 has 3 fenestration holes whereas the FP8 does not. The AGV S3 does not have fenestration holes.

o Performance Testing

Extensive non-clinical testing of the predicate AGV-FP7 has been included as a reference. The modification of the plate for the AGV-FP8 does not impact the result of the non-clinical testing. This testing was 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 primary predicate AGV-FP7 (considered to be representative or a worst case as compared to the proposed AGV-FP8) 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.

o Substantial Equivalence

There is no change in intended use and the testing performed for the Ahmed® Glaucoma Valve Model FP8 demonstrated that the performance of the device is equivalent to the legally marketed predicate devices.

o Clinical Study Results

Published clinical data for the AGV-FP8 can be found in the citations referenced below. This includes safety and effectiveness data and information on adverse effects and complications associated with the AGV-FP8.

1. Comparison of the Outcome of Silicone Ahmed Glaucoma Valve Implantation with a Surface Area between 96 and 184 mm^2 in Adult Eyes. This study was a retrospective review of records from adult refractory glaucoma patients who underwent either AGV-FP8 or AGV-FP7 implantation by two surgeons at a single center. Similar surgical techniques were used regardless of implant type. Some patients were followed up to 3 years after surgery. There were no statistically significant differences between the groups in preservation of vision, IOP reduction, or decrease in the number of glaucoma medications.

   Koh KM, Hwang YH, Jung JJ, Sohn YH, Kim HK. Comparison of the outcome of silicone Ahmed glaucoma valve implantation with a surface area between 96 and 184 mm^2 in adult eyes. Korean J Ophthalmol. 2013 Oct;27(5):361-7. PubMed PMID: 24082774; PubMed Central PMCID: PMC3782582.

2. Outcomes of Ahmed Valve Implant Following a Failed Initial Trabeculotomy and Trabeculectomy in Refractory Primary Congenital Glaucoma. This was a retrospective noncomparative case series of eyes with a diagnosis of refractory primary congenital glaucoma. The AGV-FP8 was implanted by a single surgeon after a failed primary trabeculectomy + trabeculotomy. In this difficult-to-treat group of patients, the AGV-FP8 was found to be an effective treatment.

   Dave P, Senthil S, Choudhari N, Sekhar GC. Outcomes of Ahmed valve implant following a failed

initial trabeculotomy and trabeculectomy in refractory primary congenital glaucoma. Middle East Afr J Ophthalmol. 2015 Jan-Mar;22(1):64-8. PubMed PMID: 25624676; PubMed Central PMCID: PMC4302479.

3. Combined trabeculotomy-trabeculectomy versus Ahmed valve implantation for refractory primary congenital glaucoma in Egyptian patients: a long-term follow-up. This was a randomized, prospective, single-surgeon, comparative study that included 66 eyes with refractory primary congenital glaucoma with up to four years of follow up reported. Patients had previously failed goniotomy and trabeculotomy. Half of the patients underwent a combined trabeculotomy-trabeculectomy procedure and the other half underwent AGV-FP8 implantation. Both procedures were found to be suitable options in advanced refractory primary congenital glaucoma with similar long term IOP reduction, decrease in number of glaucoma medications, and success rates. A higher rate of hyphema was reported in the combined trabeculotomy-trabeculectomy group with other rates of complications similar between the two groups.

   Helmy, Hazem. "Combined trabeculotomy-trabeculectomy versus Ahmed valve implantation for refractory primary congenital glaucoma in Egyptian patients: a long-term follow-up." *Electronic physician* 8.2 (2016): 1884.

4. Surgical outcomes of additional Ahmed glaucoma valve implantation in refractory glaucoma. Clinical histories of 23 refractory glaucoma patients, 21 of whom underwent a AGV-FP8 implantation after a failed glaucoma drainage device implantation were retrospectively reviewed. Outcomes for up to 3 years were reported. Implantation of an AGV-FP8 was described as a good choice for surgical treatment when the first glaucoma drainage device failed. Corneal decompensation was found in some cases but no other serious complications were reported.

   Ko, Sung Ju, et al. "Surgical outcomes of additional Ahmed glaucoma valve implantation in refractory glaucoma." Journal of glaucoma 25.6 (2016): e620-e624.