May 12, 2023

New World Medical, Inc.
Mr. Victor Arellano
Senior Global Regulatory Affairs Manager
19763 Edison Court
Rancho Cucamonga, California 91730

Re: K230975
Trade/Device Name: Ahmed® Glaucoma Valve Model FP7
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous shunt
Regulatory Class: Class II
Product Code: KYF
Dated: March 28, 2023
Received: April 5, 2023

Dear Mr. Arellano:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Claudine H. Krawczyk -S

for Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230975

Device Name
Ahmed® Glaucoma Valve Model FP7

Indications for Use *(Describe)*
The Ahmed® Glaucoma Valve Model FP7 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.

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510(K) SUMMARY – K230975

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92

A. Date Prepared: 05/11/2023

B. 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:

Table 1: Manufacturer & Sterilization Information

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

C. Device Name

Device Trade Name: Ahmed® Glaucoma Valve Model FP7

Common Name: Glaucoma Drainage Device

Classification Name: Aqueous Shunt (21 CFR 886.3920)

Product Code: KYF

Device Class: Class II – Ophthalmic Panel

D. Predicate Device

510 (K) Number: K162060

Device Name: Ahmed® Glaucoma Valve Model FP7

Decision date: 10/24/2016

E. Intended Use

The Ahmed® Glaucoma Valve Model FP7 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.

This is the same intended use as the previously cleared Ahmed® Glaucoma Valve FP7, 510(k) Number K162060

F. Device Description and Technological Characteristics

The Ahmed® Glaucoma Valve Model FP7 (AGV-FP7) (Modified) 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 (Original). 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 (Modified) 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 (Modified) maintains intraocular pressure within the appropriate physiological range.

G. Proposed Change

The AGV-FP7 (modified) is a modification to the AGV-FP7 (original) in which the endplate material has been changed from one grade of silicone (NuSil MED 4840) to a slightly firmer grade of silicone (NuSil MED 4850).

H. Testing

The Ahmed® Glaucoma Valve Model FP7 (Modified) was tested for Cytotoxicity, Sensitization, Irritation, Pyrogenicity, Physical Stability testing, Chemical Testing, and Aqueous Aging Testing (Hydrolytic Stability) to support the purposed change.

The results of the testing indicated that the change to the material did not pose any new risk to the device. All testing provided in the submission utilized well-established methods to evaluate the proposed change, all testing methods and acceptance criteria are the same as the proposed predicate devices.

I. Conclusion

In conclusion, the change to the endplate material to a slightly firmer grade of silicone does not raise new questions of safety and efficacy. Based on the non-clinical performance data, Ahmed® Glaucoma Valve Model FP7 (modified) described in this submission is substantially equivalent to the predicate device.