January 18, 2019

New World Medical, Inc.
Mukesh Sabarad
Manager, Regulatory Affairs
10763 Edison Ct
Rancho Cucamonga, California 91730

Re: K182518
Trade/Device Name: AHMED® ClearPath Glaucoma Drainage Device
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous Shunt
Regulatory Class: Class II
Product Code: KYF
Dated: December 14, 2018
Received: December 17, 2018

Dear Mukesh Sabarad:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tieuvi H. Nguyen -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)*
K182518

Device Name
AHMED® ClearPath Glaucoma Drainage Device

Indications for Use *(Describe)*
The AHMED® ClearPath glaucoma drainage device is indicated for the management of refractory glaucoma where previous surgical treatment has failed or is not expected to provide satisfactory results. Such refractory glaucoma may include but is not limited to: neovascular glaucoma, congenital or infantile glaucoma, and refractory glaucoma 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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510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

New World Medical, Inc
10763 Edison Ct
Rancho Cucamonga, CA 91730
USA
(909) 466-4304

Contact Person: Mukesh Sabarad
Manager, Regulatory Affairs
New World Medical, Inc.
(909) 466-4304 Ext146

Date Summary Prepared: January 17, 2019

II. DEVICE

Trade Name: AHMED® ClearPath Glaucoma Drainage Device

Common Name: Glaucoma Implant

Classification Name: Aqueous shunt (21 CFR 886.3920)

Device Class: Class II

Device Product Code: KYF

III. PREDICATE DEVICES

Predicate devices information	
510(k) Number: K905129 **Device Name**: Baerveldt Glaucoma Implant (BGI) **Decision Date**: 02/11/1991	**510(k) Number**: K955455 **Device Name**: Baerveldt Pars Plana Glaucoma Implant (BGI) **Decision Date**: 02/18/1997
Reference device information	
510(k) Number: K162060 **Device Name**: Ahmed Glaucoma Valve **Decision Date**: 10/24/2016	

IV. DEVICE DESCRIPTION

The AHMED® ClearPath Glaucoma Drainage Device is a non-valved drainage device designed to shunt aqueous in eyes suffering from refractory glaucoma. Two models CP250 and CP350 are available covering surface areas of approximately 250mm^2 and 350mm^2. The implant consists of a medical grade silicone tube secured to a medical grade silicone episcleral plate near the anterior suture points. The anterior suture points are located on the anterior side of the plate, flanking each side of the tubing track. The silicone plate is barium impregnated to increase ultrasound resolution and identification with CT scan, MRI and plain skull films. The plate conforms to the shape of the globe at its equator and provides a surface from which fluid can be dispersed. Each AHMED® ClearPath is supplied with a 23-gauge hypodermic needle and a 2-inch polypropylene ripcord (pre-loaded in the lumen of the tube) in a sterile, sealed double- pouch. The supplied needle and ripcord are for optional use and are available to be incorporated into the implantation procedure per the surgeon's usual routine. The device is for single use only.

V. INTENDED USE

The AHMED® ClearPath glaucoma drainage device has the same intended use as the predicates and all other devices regulated within the generic type of device known as aqueous shunts in accordance with 21 CFR 886.3920. The device is a prescription (Rx) device that is intended to be permanently implanted to reduce intraocular pressure for the management of refractory glaucoma.The AHMED® ClearPath glaucoma drainage device will bear the following indications for use statement:

The AHMED® ClearPath glaucoma drainage device is indicated for the management of refractory glaucoma where previous surgical treatment has failed or is not expected to provide satisfactory results. Such refractory glaucoma may include but is not limited to: neovascular glaucoma, congenital or infantile glaucoma, and refractory glaucoma resulting from aphakia or uveitis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological characteristics of the AHMED® ClearPath glaucoma drainage device and the Baerveldt glaucoma implant are similar. Furthermore, the differences in technological characteristics that exist between the AHMED® ClearPath glaucoma drainage device and both legally marketed predicate devices do not raise different questions of safety and effectiveness.

Comparison of the AHMED® ClearPath glaucoma drainage device and the Predicate Devices

Feature	AHMED® ClearPath (ACP)	Baerveldt Glaucoma Implant (BGI)
Intended Use	To be permanently implanted to reduce intraocular pressure for the management of Glaucoma	To be permanently implanted to reduce intraocular pressure for the management of Glaucoma
Indication for Use	The AHMED® ClearPath Glaucoma Drainage Device is indicated for the management of refractory glaucoma where previous surgical treatment has failed or is not expected to provide satisfactory results. Such refractory glaucoma may include but is not limited to neovascular glaucoma, congenital or infantile glaucoma, and refractory glaucoma resulting from aphakia or uveitis.	The Baerveldt Glaucoma Implant is indicated for use in patients (with prior vitrectomy for Pars Plana) with medically uncontrollable glaucoma and poor surgical prognosis, such as, but not limited to: neovascular glaucoma, aphakic/pseudophakic glaucomas, patients who have failed conventional surgery, congenital glaucomas and secondary glaucomas due to uveitis, epithelial downgrowth, etc.
Regulation Number/Product Code	886.3920, KYF	886.3920, KYF
Rx or OTC	Rx	Rx
Permanent Implant	Yes	Yes
Anatomical Site	The tube is implanted in the anterior chamber and the endplate is implanted under the conjunctiva	The tube is implanted in the anterior chamber and the endplate is implanted under the conjunctiva
Material (endplate)	Medical grade silicone, barium impregnated	Medical grade silicone, barium impregnated
Material (tube)	Medical grade silicone	Medical grade silicone
Location of anterior suturing holes (relative to the limbus)	6-8mm	8-10 mm for model BG101-350 and BG103-250. Model BG102-350 with Pars Plana Clip it is 2-7mm
Mechanism of action	Creates a channel via a tube for aqueous flow from the anterior chamber to the subconjunctival space resulting in a bleb formed within the encapsulated polypropylene.	Creates a channel via a tube for aqueous flow from the anterior chamber to the subconjunctival space resulting in a bleb formed within the encapsulated polypropylene
Design	Silicone tube attached to a silicone endplate	Silicone tube attached to a silicone endplate
Plate Footprint Area (Surface area)	250 mm^2 and 350 mm^2	250 mm^2 and 350 mm^2
Tube Dimensions	Length: 32 mm Inner diameter: 0.30 mm Outer Diameter: 0.63 mm	Length: 32 mm Inner diameter: 0.305 mm Outer Diameter: 0.635 mm

Feature	AHMED® ClearPath (ACP)	Baerveldt Glaucoma Implant (BGI)
Plate Thickness	0.81mm	0.84mm (1.5mm for the Pars-Plana Clip)
Sterilization	Gamma	Gamma
How Supplied	Sterile	Sterile
Single Use	Yes	Yes

VII. PERFORMANCE DATA

Bench Testing:

The nonclinical bench testing conducted on the AHMED® ClearPath glaucoma drainage device included design verification and functional product testing, sterilization validation, packaging and shelf life testing, and biocompatibility testing. Results of the nonclinical testing demonstrate that the AHMED® ClearPath glaucoma drainage device meets the defined specifications.

Design Verification and Functional Product Testing:

The AHMED® ClearPath glaucoma drainage device was evaluated to verify that the design output met the original design input and intent. This testing was based on tests described in ANSI Z80.27, Implantable Glaucoma Devices, which includes: pressure/flow characterization, structural integrity, and dimensional verification. The results establish that the AHMED® ClearPath glaucoma drainage device meets the design intent and complies with the applicable requirements.

Device Performance Comparison to Predicate Device Baerveldt Glaucoma Implant

The AHMED® ClearPath glaucoma drainage device was evaluated against the predicate Baerveldt Glaucoma Implant for pressure/flow characterization and effectiveness of tube occlusion utilizing a ripcord. The results establish that the AHMED® ClearPath glaucoma drainage device and Baerveldt Glaucoma Implant are equivalent.

Sterilization Validation:

The gamma irradiation sterilization method was validated using the VD_{max}^{15} method described in BS EN ISO 11137-1:2015 and BS EN ISO 11137-2:2015. Validation results demonstrate that a minimum exposure dose of 15 kGy has been substantiated for the routine sterilization of the AHMED® ClearPath glaucoma drainage device to provide a 10^{-6} sterility assurance level (SAL).

Packaging and Shelf Life Testing:

The AHMED® ClearPath glaucoma drainage device is labeled with an expiration date of 2 (two) years. The shelf life study evaluated the functional performance of the AHMED® ClearPath glaucoma drainage device, as well as the packaging integrity. Additional testing was completed to evaluate the impact of environmental conditioning and distribution factors. Test results confirm that the AHMED® ClearPath glaucoma drainage device meet their functional requirements and the sterile barrier (package integrity) remains intact after simulated distribution and aging. This testing provides the justification for the 2-year shelf life and the maintenance of the sterile barrier.

Biocompatibility Testing

Biocompatibility of the final finished AHMED® ClearPath glaucoma drainage device was demonstrated through testing in accordance with BS EN ISO 10993-1 "Biological evaluation of medical devices, Part 1: Evaluation and testing within a risk management process" (refer to the table below for a listing of all tests performed). Testing was performed for the Implant, Ripcord, and Hypodermic Needle. The testing demonstrated that the device materials have an acceptable biocompatibility profile.

Listing of All Biocompatibility Tests Performed on All Patient Contacting Materials

Test	Results
Cytotoxicity (MEM Elution)	Non-cytotoxic
Guinea Pig Maximization Sensitization	Non-irritant compared to negative control
Acute Systemic Toxicity (Mouse)	Non-toxic
Intraocular Irritation (Rabbit)	No evidence of irritation
Bacterial Mutagenicity – Ames Assay	Non-mutagenic
4 Week Intramuscular Implant (Rabbit)	Non-irritant compared to USP negative control
13 Week Intramuscular Implant (Rabbit)	Non-irritant compared to USP negative control
Material mediated pyrogenecity	Non-pyrogenic
Direct Contact Cytotoxicity	Non-cytotoxic

Clinical Evidence Supporting Substantial Equivalence

Although the AHMED® ClearPath has not been clinically evaluated for performance, the following reference in the published clinical literature summarizes the performance of the predicate Baerveldt Glaucoma Implant.

- Budenz, Donald L., et al. "Five-year treatment outcomes in the Ahmed Baerveldt comparison study." *Ophthalmology* 122.2 (2015): 308-316.

The following additional clinical literature is referenced in support of differences in design of the AHMED® ClearPath as compared to the predicate Baerveldt Glaucoma Implant.

- Placement of Device: This study was conducted to determine optimal positioning of various glaucoma drainage devices posterior to the limbus while maintaining a safe distance relative to the optic nerve.

  - Kahook, Malik Y., et al. "Location of glaucoma drainage devices relative to the optic nerve." *British Journal of Ophthalmology* 90.8 (2006): 1010-1013.

- Implant Design – Ridge: The following studies evaluated the safety and effectiveness of the AGV-FP7 reference device to the predicate Baerveldt Glaucoma Implant and indicate that a lack of a ridge does not significantly impact implant performance.

  - Budenz, Donald L., et al. "Five-year treatment outcomes in the Ahmed Baerveldt comparison study." *Ophthalmology* 122.2 (2015): 308-316.

  - Budenz, Donald L., et al. "Postoperative complications in the Ahmed Baerveldt comparison study during five years of follow-up." *American Journal of Ophthalmology* 163 (2016): 75-82.

- Use of Ripcord for Tube Occlusion: A ripcord for optional use is provided within the tube lumen of the Ahmed ClearPath device. Tube occlusion via intraluminal ripcord is a common technique to prevent early postoperative hypotony in non-valved glaucoma drainage devices. Below are examples of medical publications that discuss this technique, its effectiveness and its impact on implant performance.

  - Sherwood, Mark B., and M. Fran Smith. "Prevention of early hypotony associated with Molteno implants by a new occluding stent technique." *Ophthalmology* 100.1 (1993): 85-90.

  - An, Selena J., et al. "Scheduled postoperative ripcord removal in Baerveldt 350 implants corresponds with increased complications: a prospective, randomized trial." *Investigative Ophthalmology & Visual Science* 59.9 (2018): 2073-2073.

VIII. SUBSTANTIAL EQUIVALENCE

The AHMED® ClearPath glaucoma drainage device has the same intended use as the legally marketed predicate devices identified in this 510(k) submission and all other aqueous shunts regulated by FDA under 21 CFR § 886.3920. The provision of the 23-gauge hypodermic needle and the 2-inch polypropylene ripcord for use (optional) with the AHMED® ClearPath glaucoma drainage device during the implantation procedure does not represent a departure from the standard of care because their use is common with non-valved shunt designs including the Baerveldt the predicate device.

Results of the nonclinical testing demonstrate that the AHMED® ClearPath glaucoma drainage

device meets the defined specifications. In summary, the AHMED® ClearPath glaucoma drainage device is substantially equivalent to the Baerveldt glaucoma implant when used in the management of refractory glaucoma.