March 31, 2020

HR Pharmaceuticals, Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, MN 55114

Re: K200556
Trade/Device Name: AquaFlate Pre-Filled Sterile Water Syringe 10mL
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: March 2, 2020
Received: March 3, 2020

Dear Prithul Bom:

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,

Jessica K. Nguyen, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200556

Device Name
AquaFlate Pre-filled Sterile Water Syringe 10 mL

Indications for Use *(Describe)*
The AquaFlate Pre-filled Sterile Water Syringe is intended to be used for inflating a Foley catheter balloon.

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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5.0 510(k) SUMMARY

510(k) SUMMARY
for
AquaFlate Pre-Filled Sterile Water Syringe 10mL

I. SUBMITTER:

HR Pharmaceuticals, Inc.
2600 Eastern Boulevard, Suite 201
York, PA 17402

Telephone Number:717-252-1110 x104
Fax Number:717-685-2590

Contact Person: Colby Wiesman
Date Prepared: November 26, 2019

II. DEVICE:

Name of Device: AquaFlate Pre-Filled Sterile Water Syringe 10mL
Model Number: 250-400
Common or Usual Name: Catheter, Retention type, balloon
Classification Description: Urological catheter and accessories (21 CFR 876.5130)
Regulatory Class: II
Product Code: EZL
Review Panel: Gastroenterology/Urology

III. PREDICATE DEVICES:

AMSINO INTERNATIONAL, AMSure® Prefilled Syringe for Balloon Inflation with Sterile Water, K181814

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION:

The proposed device, AquaFlate Pre-Filled Sterile Water Syringe 10mL (REF 250-400), is a 10mL syringe prefilled with USP purified water and sterilized via gamma irradiation. The syringe consists of a polypropylene barrel and plunger and latex free rubber for both the plunger gasket and syringe tip cap.

The AquaFlate Pre-Filled Water Syringe 10mL is intended for inflating an indwelling, urethral Foley catheter balloon. In accordance with CDC Guidelines, healthcare facility protocols, and the Foley catheter manufacturer's instructions for use, prior to catheterization, the syringe cap of the AquaFlate Pre-Filled Sterile Water Syringe 10mL is

removed and the luer tip of the syringe is connected to the inflation port of the catheter. Once the catheter is inserted into the bladder, the entire contents of the syringe are dispensed to inflate the catheter balloon to ensure the catheter does not slide out. After balloon inflation, the syringe is disconnected from the catheter inflation port and discarded.

The AquaFlate Pre-Filled Sterile Water Syringe 10mL is not intended for injection and is for single use only.

The shelf life of the AquaFlate Pre-Filled Sterile Water Syringe 10mL is one (1) year.

HR Pharmaceuticals does not intend to market this device with accessories or as part of a system.

V. INDICATIONS FOR USE:

The AquaFlate Pre-Filled Sterile Water Syringe 10mL is intended to be used for inflating a Foley catheter balloon.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES:

The subject and predicate devices have the same technological principle whereby, the prefilled sterile water syringe is intended for inflating an indwelling, urethral Foley catheter balloon. Once the catheter is inserted into the bladder, the entire contents of the syringe are dispensed to inflate the catheter balloon to ensure the catheter does not slide out. After balloon inflation, the syringe is disconnected from the catheter inflation port and discarded. Additionally, the prefilled sterile water syringe is not intended for injection and is for single use only.

At a high level, the AquaFlate Pre-Filled Sterile Water Syringe 10mL and the predicate device are based on the following same elements:

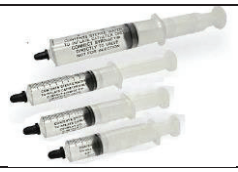
- Same Intended Use
- Same Technological Characteristics
- Same Materials
- Same Physical Characteristics
- Same Performance Specifications
- Packaged in the same quantity (10mL)
- Provided sterile
- Biocompatible

The only identified difference between the subject and predicate devices is the shelf life. The AquaFlate Pre-Filled Sterile Water Syringe 10mL has a one-year shelf life whereby, AMSure® Prefilled Syringe for Balloon Inflation with Sterile Water has a three-year shelf life. While the AquaFlate Pre-Filled Sterile Water Syringe 10mL is currently undergoing 2 year and 3-year shelf life testing, the one-year established shelf life for the subject device is acceptable for the intended use as demonstrated by successful stability

and performance testing. Therefore, the difference in shelf life between the subject and predicate devices does not raise new questions of safety or effectiveness.

A more detailed comparison of the predicate and subject devices is presented in the table below.

		Proposed Device AquaFlate Pre-Filled Sterile Water Syringe 10mL	**Predicate Device AMSure Prefilled Syringe for Balloon Inflation with Sterile Water (K181814)**	**Comparison**
Manufacturer		HR Pharmaceuticals, Inc.	Amsino International, Inc.	N/A
Device Classification Name		Catheter, Retention Type, Balloon	Catheter, Retention Type, Balloon	Same
Regulation Description		Urological catheter and accessories	Urological catheter and accessories	Same
Review Panel		Gastroenterology/Urology	Gastroenterology/Urology	Same
Product Code		EZL	EZL	Same
Reg Number		876.5130	876.5130	Same
Class		II	II	Same
Indications for Use		The AquaFlate Pre-Filled Sterile Water Syringe 10mL is intended to be used for inflating a Foley catheter balloon.	Prefilled Syringe for Balloon Inflation with Sterile Water is intended to be used in inflating foley catheter balloon.	Same
Patient-contacting material		Indirect patient contact of sterile water used to inflate a catheter balloon	Indirect patient contact of sterile water used to inflate a catheter balloon	Same
Sizes		10mL	10cc and 30cc	Same (10mL)
Materials of Main Components	Barrel	Polypropylene	Polypropylene	Same
	Plunger	Polypropylene	Polypropylene	Same
	Plunger Gasket	Isoprene (black synthetic rubber that does not contain natural rubber latex)	Black pharmaceutical grade, synthetic rubber (Latex free)	Same
	Tip Cover	Isoprene (black synthetic rubber that does not contain natural rubber latex)	Same as gasket	Same
	Solution	Purified water, USP	Purified water, USP	Same
Principle of Operation		Manual	Manual	Same
Technical Performance		Conforms with ISO7886-1, ISO 80369-7 and USP 42 Chapter <71>	Conforms with ISO7886-1, ISO 80369-7 and USP 40	Same
Biocompatibility		Meets ISO 10993-1:2009 requirements for irritation (ISO 10993-10), sensitization (ISO	Conforms with ISO 10993-5 and ISO 10993-10	Same

	Proposed Device AquaFlate Pre-Filled Sterile Water Syringe 10mL	**Predicate Device AMSure Prefilled Syringe for Balloon Inflation with Sterile Water (K181814)**	**Comparison**
	10993-10), and cytotoxicity (ISO 10993-5)		
Utility	Single Use	Single Use	Same
Sterility (Method)	Sterile (Gamma Irradiation)	Sterile (Gamma Irradiation)	Same
Environment of Use	Healthcare Facility	Healthcare Facility	Same
Labeling	Prescription Use	Prescription Use	Same
Shelf Life	1 year	3 years	Different
Device Picture			N/A

*Values obtained from performance testing conducted per HR Pharmaceuticals' protocols.

VII. PERFORMANCE DATA

There are no FDA device-specific guidance documents, special controls document, and/or requirements in a device-specific regulation for prefilled sterile water syringes. Additionally, no performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for prefilled sterile water syringes. However, the following performance data were provided in support of the substantial equivalence determination.

Bench Testing

- **Small-bore connector testing** – ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications [FR Recognition No. 5-115]
- **Manual, single-use syringe testing** – ISO 7886-1:2017, Sterile hypodermic syringes for single use — Part 1: Syringes for manual use [FR Recognition No. 6-404]
- **Sterility** – USP 42 Chapter <71> - Sterility Tests [FR Recognition No. 14-532]

Biocompatibility Testing

The biocompatibility evaluation for the AquaFlate Pre-Filled Sterile Water Syringe 10mL was conducted in accordance with the FDA Final Guidance "Use of International Standard ISO-10993, 'Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process,'" June 16, 2016, and International Standard ISO 10993-1:2009 "Biological Evaluation of Medical Devices − Part 1: Evaluation and

Testing Within a Risk Management Process," as recognized by FDA. The biocompatibility testing included the following and yielded acceptable results:

- **Cytotoxicity** - ANSI/AAMI/ISO 10993-5:2009 (R) 2014 Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity [FR Recognition No. 2-245]
- **Irritation** - ANSI/AAMI/ISO 10993-10:2013—Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization [FR Recognition No. 2-174]
- **Sensitization** - ANSI/AAMI/ISO 10993-10:2013—Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization [FR Recognition No. 2-174]

The AquaFlate Pre-Filled Sterile Water Syringe 10mL falls into the category of limited (<24 hour) external communicating devices and is intended for indirect tissue contact.

Sterilization

The AquaFlate Pre-Filled Sterile Water Syringe 10mL was validated for sterilization using gamma irradiation at a minimum dose of 25kGy and a maximum dose of 40kGy to achieve a Sterility Assurance Level of 10^{-6} in accordance with the following recognized standards:

- ANSI/ AAMI/ISO 11137-1:2006/(R) 2015 & A1:2013. Sterilization of health care products -Radiation-Part1: Requirements for development validation, and routine control of a sterilization process for medical devices. [FR Recognition No. 14-428]
- ANSI/AAMI/ISO 11137-2:2013. Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose. [FR Recognition No. 14-409]
- ANSI/AAMl/ISO 11137-3:2006 (R) 2010. Sterilization of healthcare products - Radiation-Part 3: Guidance on dosimetric aspects. [FR Recognition No. 14-510]
- ANSI/AAMl/ISO 11737-1: 2018. Sterilization of health care products, Microbiological Methods-Part l: Determination of a population of microorganisms on product. [FR Recognition No. 14-514]
- ANSI/AAMI/ISO 11737-2: 2009 (R) 2014. Sterilization of Medical Devices-Microbiological Methods-Part 2: Tests of sterility Performed in the definition, validation and maintenance of a sterilization Process. [FR Recognition No. 14-327]
- AAMI TIR 17-2008. Compatibility of Materials subject to sterilization.
- ANSI/AAMI/ISO TIR13004: 2013. Sterilization of health care products-Radiation-Substantiation of a selected sterilization dose-Method $VDmax^{SD}$.

Packaging Validation and Shelf Life

The AquaFlate Pre-Filled Sterile Water Syringe 10mL underwent packaging validation testing and accelerated aging testing per the below standards to support a one-year shelf life.

- ISTA Procedure 3A (2018) Series. General Simulation Performance Test Procedure Packaged-Products for Parcel Delivery System Shipment 150lb or less.
- ASTM D4169-16. Performance Testing of Shipping Containers and Systems [FR Recognition No. 14-499]
- ASTM F1980-16. Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices [FR Recognition No. 14-497]

VIII. CONCLUSION

All necessary testing has been performed on the AquaFlate Pre-Filled Sterile Water Syringe 10mL to support the safety and effectiveness of the device per its intended use. Additionally, the performance testing concluded that the subject device is substantially equivalent to the legally marketed predicate device.