December 15, 2020

Hangzhou Primecare Medical Co., Ltd.
℅ Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street, Panyu District
Guangzhou, Guangdong 510006
China

Re: K202698
Trade/Device Name: Prefilled Syringe
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: September 11, 2020
Received: September 16, 2020

Dear Olivia Meng:

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,

Sharon M. Andrews
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202698

Device Name
Prefilled Syringe

Indications for Use *(Describe)*
The 10cc and 30cc pre-filled syringes are intended to be used for foley catheter balloon inflation.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K202698

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

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Date prepared	December 15, 2020

2. DEVICE

Device Name:	Prefilled Syringe
Common name:	Prefilled Syringe
Model:	PCAA01, PCAA03
Regulation Number	21 CFR 876.5130
Regulation Name	Urological catheter and accessories
Regulatory Class:	2
Product Code:	EZL
Product Code Name:	Catheter, Retention Type, Balloon

3. PREDICATE DEVICE

K030813, Primary Care Solutions Prefilled 10cc and Prefilled 30cc Inflation Syringes with Sterile Water; Catalog numbers 1010 and 1030 respectively This predicate has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The device is a single-use 10cc and 30cc syringe pre-filled with USP purified water and gamma irradiated. The device has two models, PCAA01 and PCAA03. They are only different in volume; PCAA01 is 10cc, and PCAA03 is 30cc. The syringe is produced using polypropylene for the device barrel and plunger and pharmaceutical grade latex free rubber for both the plunger gasket and protect cap. The device contacts indirectly with the human body. The duration of contact is less than 24 hours. The product is used in conjunction with the urinary catheter to push the plunger of the syringe to inject the sterilized pre-filled purified water into the balloon of the urinary catheter to inflate the balloon.

5. INDICATIONS FOR USE

The 10cc and 30cc pre-filled syringes are intended to be used for foley catheter balloon inflation.

The intended use of the device is the same as the intended use of the predicate device.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

		Predicate Device	**Proposed Device**	**Discussion of Differences**
Device name		Primary Care Solutions Prefilled 10cc and Prefilled 30cc Inflation Syringes with Sterile Water;	Prefilled Syringe	
K number		K030813	K202698	
Size		10cc and 30cc	10cc and 30cc	Same
Principle of operation		Manual	Manual	Same
Design		Conforms with ISO 7886.1 and ISO 80369-7	Conforms with ISO 7886.1 and ISO 80369-7	Same
Disposable?		Disposable for single use	Disposable for single use	Same
Materials Of	Barrel	Polypropylene	Polypropylene	Same

Main Components	Plunger	Polypropylene	Polypropylene	
	Stopper	Pharmaceutical Grade Latex Free Rubber	Pharmaceutical Grade Latex Free Rubber	
	Protective Cap	Pharmaceutical Grade Latex Free Rubber	Pharmaceutical Grade Latex Free Rubber	
	Solution	Purified Water, USP	Purified Water, USP	
Sterile?		Sterile (gamma irradiation)	Sterile (gamma irradiation)	Same

As evidenced by the table above, the subject and predicate device have similar technological characteristics.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Prefilled Syringe was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity - (ISO 10993-5: 2009)
- Sensitization - (ISO 10993-10:2010)
- Irritation - (ISO 10993-10:2010)

Performance testing

Performance testing was conducted on the Prefilled Syringe according to the following standards:

1. ISO 7886-1: 2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
2. ISO 11040-8: 2016 Prefilled Syringes - Requirements and test methods for finished prefilled syringes
3. ISO 11040-4: 2015 Prefilled Syringes - Glass barrels for injectables and sterilized subassembled syringes ready for filling

4. ISO 11040-6: 2019 Prefilled Syringes - Plastic barrels for injectables and sterilized subassembled syringes ready for filling
5. ISO 80369-1: 2018 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
6. ISO 80369-7: 2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
7. ISO 80369-20: 2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
8. USP 40 - Purified Water <6719>

All of the tested parameters met the predefined acceptance criteria.

8. CONCLUSION

From the results of non-clinical data including the performance testing described, it is concluded that the Prefilled Syringe is as safe and as effective as the predicate device. The information provided within this pre-market notification demonstrates that the device is substantially equivalent to the predicate device.