DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 22, 2016

Wuxi Yushou Medical Appliances Co., Ltd
% Jun Peng
Principal Consultant
P&L Scientific Inc.
6840 SW 45th Ln Unit 5
Miami, Florida 33155

Re: K152906
Trade/Device Name: Disposable High Pressure Injector Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: February 19, 2016
Received: March 2, 2016

Dear Jun Peng:

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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152906

Device Name
Disposable High Pressure Injector Syringe

Indications for Use *(Describe)*
Disposable High Pressure Injector Syringe is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

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

510(k) summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based:

The Assigned 510(k) Number is: k152906

1. Submitter Information:

- **Sponsor/510(K) Owner:**
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  Dated: May 4, 2016

- **Contact Name:**
  Mr. Jun Peng
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2. Device Name

Trade Name: Disposable High Pressure Injector Syringe
Common Name: Angiographic Injector and Syringe

3. Classification:

Classification Names	**FR Number**	**Product Code**
Injector and syringe, angiographic	870.1650	DXT

4. Predicate Devices:

Name	K number	Manufacturer information
DISPOSABLE ANGIOGRAPHIC SYRINGE MODEL(S) CT-200-NE CT-200-MA CT-200+200-MA CT-200-LF CT -100-NE CT-200NE CT-50+CT	K082439	SHANDONG WEIGAO MEDICAL POLYMER CO. LTD
ANT ANGIOGRAPHIC SYRINGES MODEL(S) 1001011021031002012022032041003012001012012022032003011011022023 01	K072696	SHENZHEN ANT HI-TECH INDUSTRIAL CO. LTD

5. Description of Device

The product has two types: one type is composed of one or several syringes and one or several accessories. The accessories include connecting tube and medicine aspirator (punctured medicine aspirator and tubular medicine aspirator); the other type is composed of individual accessory; the syringe is composed of barrel, plunger, piston or plunger cap. The connecting tube has one-way and multi-way. One-way connecting tube is composed of locking connector, tubing, female conical fitting, nozzle cap, protective cap or one-way valve; multi-way connecting tube is composed of multi-way connector, locking connector, tubing, female conical fitting, nozzle cap, protective cap, one-way valve or puncture.

Maximum rated pressure for the Disposable High Pressure Injector Syringe is either 300psi (2.07MPa) or 1200psi (8.3MPa). The rated pressure for each models are listed in the following *Models and Combinations* Table.

The aspirator has tubular medicine aspirator and punctured medicine aspirator. Punctured medicine aspirator has plastic pin.

Product packaging: Primary package is heat-sealed by Tyvek paper and PS blister.

The following configurations of various syringes and accessories are available than are in compatible with market available injectors from Medrad, Liebel-Flarsheim, Acist or Nemoto.

Models and combinations

Models	**Composition**	**Compatible with**	**Maximum Rated Pressure**
10060A/ 10060A	2-65ml Syringe 1-255cm Multi-way Connecting Tube 2-Punctured Medicine Aspirator	MEDRAD SOLARIS& SPECTRIS MRI	300psi
10060C/ 10060C	2-60ml Syringe 1-255cm Multi-way Connecting Tube 2-Punctured Medicine Aspirator	Liebel-Flarsheim Optistar MRI	300psi
100100C/ 10060A	1-115ml Syringe 1-65ml Syringe 1-255cm Multi-way Connecting Tube 2-Punctured Medicine Aspirator	MEDRAD SOLARIS& SPECTRIS MRI	300psi
100100C/100100C	2-115ml Syringe 1-255cm Multi-way Connecting Tube 2-Punctured Medicine Aspirator	MEDRAD SOLARIS& SPECTRIS MRI	300psi
100100A	1-100ml Syringe	MEDRAD MCT PLUS CT	300psi

	1-150cmOne-way Connecting Tube 1-J-type Tubular Medicine Aspirator	MEDRAD VISTRON CT MEDRAD ENVISION CT	
100100B	1-100ml Syringe 1-150cm One-way Connecting Tube 1-J-type Tubular Medicine Aspirator	MEDRAD MCT PLUS CT MEDRAD VISTRON CT MEDRAD ENVISION CT	300psi
100100D	1-100ml Syringe 1-J-type Tubular Medicine Aspirator	Liebel-Flarsheim 3000 Series DSA	1200psi
100130A	1-130ml Syringe 1-J-type Tubular Medicine Aspirator	MEDRAD MARK IV & MARK III DSA	1200psi
100150A	1-150ml Syringe 1-J-type Tubular Medicine Aspirator	MEDRAD MARK V DSA MEDRAD MARK V Provis DSA	1200psi
100150C	1-150ml Syringe 1-J-type Tubular Medicine Aspirator	MEDRAD MARK 7 DSA	1200psi
100200A	1-200ml Syringe 1-150cm One-way Connecting Tube 1-J-type Tubular Medicine Aspirator	MEDRAD MCT PLUS CT MEDRAD VISTRON CT MEDRAD ENVISION CT	300psi
100200B	1-200ml Syringe 1-150cm One-way Connecting Tube 1-10cm Straight Tube 1-J-type Tubular Medicine Aspirator	MEDRAD STELLANT Single CT	300psi
100200B/ 100200B	2-200ml Syringe 1-J-type Tubular Medicine Aspirator 1-150cm Multi-way Connecting Tube 2-10cm Straight Tube 2-Punctured Medicine Aspirator	MEDRAD STELLANT Double CT	300psi
100200D	1-200ml Syringe 1-J-type Tubular Medicine Aspirator	MEDRAD MARK V DSA MEDRAD MARK V Provis DSA	1200psi
101100A/ 101100A	2-100ml Syringe 1-255cm Multi-way Connecting Tube 2-Punctured Medicine Aspirator	ACIST-MR EZEM INC-CT	300psi
101200A	1-200ml Syringe 1-150cm One-way Connecting Tube 1-J-type Tubular Medicine	ACIST-CT EZEM INC-CT	300psi

	Aspirator		
101200A/ 101200A	2-200ml Syringe 1-255cmMulti-way Connecting Tube 2-Punctured Medicine Aspirator	ACIST-CT EZEM INC-CT	300psi
200150A	1-150ml Syringe 1-J-type Tubular Medicine Aspirator	Liebel-Flarsheim Angionmat lllumena DSA	1200psi
200150B	1-150ml Syringe 1-J-type Tubular Medicine Aspirator	Liebel-Flarsheim Angionmat 6000 DSA	1200psi
200200A	1-200ml Syringe 1-150cm One-way Connecting Tube 1-J-type Tubular Medicine Aspirator	Liebel-Flarsheim CT9000 Single	300psi
200200A/ 200200A	2-200ml Syringe 1-150cm Multi-way Connecting Tube 1-J-type Tubular Medicine Aspirator 1-Punctured Medicine Aspirator	Liebel-Flarsheim CT9000 Double	300psi
300130A	1-130ml Syringe 1-J-type Tubular Medicine Aspirator	NEMOTO 120S DSA	1200psi
300100B	1-100ml Syringe 1-150cm One-way Connecting Tube 1-J-type Tubular Medicine Aspirator	NEMOTO A-25，A-60，Dual Shot CT	300psi
300100B/ 300100B	2-100ml Syringe 1-150cm Multi-way Connecting Tube 1-J-type Tubular Medicine Aspirator 1-Punctured Medicine Aspirator	NEMOTO A-25，A-60，Dual Shot CT	300psi
300200B	1-200ml Syringe 1-150cm One-way Connecting Tube 1-J-type Tubular Medicine Aspirator	NEMOTO A-25，A-60，Dual Shot CT	300psi
300200B/ 100060B	1-200ml Syringe 1-60ml Syringe 1-150cm Multi-way Connecting Tube 1-J-type Tubular Medicine Aspirator 1-Punctured Medicine Aspirator	NEMOTO Dual Shot, Dual Shot Alpha CT	300psi
300200B/ 300100B	1-200ml Syringe 1-100ml Syringe	NEMOTO Dual Shot, Dual Shot Alpha CT	300psi

	1-150cm Multi-way Connecting Tube 1-J-type Tubular Medicine Aspirator 1-Punctured Medicine Aspirator		
300200B/ 300200B	2-200ml Syringe 1-150cm Multi-way Connecting Tube 1-J-type Tubular Medicine Aspirator 1-Punctured Medicine Aspirator	NEMOTO Dual Shot, Dual Shot Alpha CT	300psi
100060B/ 100060B	2-60ml Syringe 1-255cmMulti-way Connecting Tube 2-Punctured Medicine Aspirator	NEMOTO Sonic Shot 50 MRI	300psi

6. Intended Use

Disposable High Pressure Injector Syringe is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

7. Summary of Comparison in Technological Characteristics to Predicate Device

The Disposable High Pressure Injector Syringe is substantially equivalent to the predicate device ANT Angiographic Syringes (K072696) and DISPOSABLE ANGIOGRAPHIC SYRINGE MODEL(S) CT-200-NE CT-200-MA CT-200+200-MA CT-200-LF CT -100-NE CT-200NE CT-50+CT (k082439). The subject device and the predicate device are both of the

- same intended use,
- the method of use,
- device construction,
- materials used,
- packaging,
- biological characteristics,
- and performance

8. Discussion of major difference vs. predicate device

Difference between subject device and predicate devices:

- Combination of syringes of volumes is different;
- Connection nozzles are different.

9. Assessment of Non-Clinical Testing:

The performance shows the subject device and predicate devices have the substantial equivalent performance. Therefore, the Disposable High Pressure Injector Syringe is

substantially equivalent to the predicate devices, there are no safety issues raised, and the device meets the requirements for FDA 510(k) clearance.

Performance testing:

1) Maximum Rated Pressure Testing
2) Connection Strength Test
3) Compatibility Testing between the Injector and Syringes
4) Aged Verification
5) Biocompatibility Tests
   - ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
   - ISO 10993-5:1999 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
   - ISO 10993-10:2002 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
   - ISO 10993-7: 2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
6) Transportation Validation
   - ASTM D4169 - 14 Standard Practice for Performance Testing of Shipping Containers and Systems

10. Assessment of Clinical Testing:

The clinical testing is used to evaluate the performance of the high pressure syringe and injectors, the following are evaluated:

1) Appearance
2) Sliding Performance
3) Sealing
4) Fitting

The Disposable High Pressure Injector Syringe was found to have a substantial equivalent profile that is similar to the predicate device.

11. Conclusion

After analyzing both bench and external laboratory testing data, the intended use and supporting data can conclude that the device in the submission is substantial equivalent as the predicate devices.