DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 5, 2015

Beijing Demax Medical Technology Co., Ltd.
% Mike Gu
Regulatory Affairs Manager
Osmunda Medical Device Consulting Co., LTD.
7th Floor, Jingui Business Building, No 982,
Congyun Road Baiyun District
Guangzhou, 510420 CN

Re: K140943
Trade/Device Name: Mastro Plus Balloon In-deflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: MAV
Dated: February 2, 2015
Received: February 4, 2015

Dear Mike Gu,

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,

Melissa A. Torres -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 on last page.

510(k) Number *(if known)*
K140943

Device Name
Mastro Plus Balloon in-deflation device

Indications for Use *(Describe)*

The Balloon In-deflation device is used for the inflation and deflation of a balloon dilatation catheter, to dilate the vessel or implant a stent.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92, the following summary of information is provided:

Date: March 13, 2014

Submitter: BEIJING DEMAX MEDICAL TECHNOLOGY CO., LTD.

Add: A13-7, Jingshengnansi Street,Tongzhou District, Beijing, 101102, P.R.China

Primary Contact Person: Mike Gu

Regulatory Affairs Manager

OSMUNDA Medical Device Consulting Co., Ltd.

Tel: (+86) 20-6232 1333

Fax: (+86) 20-8633 0253

Email: mike.gu@osmundacn.com

Secondary Contact Person: Ellen Bian

Regulation Affairs Dept. Manager

BEIJING DEMAX MEDICAL TECHNOLOGY CO., LTD.

Tel: (+86) 10-5977 1799-816

Fax: +86-10-5977 1883

Email: bianyuejing@demax.cn

Device: Trade Name: Mastro™ Plus Balloon In-Deflation Device

Common/Usual Name: Inflation Syringe

Classification Names: Angiographic injector and syringe

Product Code: MAV

Regulation number 870.1650

Predicate Device(s): K130566, K032840 and K993341

Device Description: The Balloon In-deflation Device is a 20ml or 30ml disposable device capable of producing a maximum pressure of 30atm/bars. It is fitted with a threaded plunger, a flexible high pressure extension tube, and a three-way high pressure stopcock. The luminescent pressure gauge with adjustable angle allows physician to read and monitor more easily in clinical environment. The product is designed under ergonomic principle that could be handled comfortably, easily and securely.

Intended Use: The Balloon In-deflation device is used for the inflation and deflation of a balloon dilatation catheter, to dilate the vessel or implant a stent.

Technology: The balloon in-deflation device mainly composes of four parts, injecting system (syringe), pressure gauge and extension tube, 3-way stopcock, respectively. The syringe consists of a screw type plunger and a locking lever, by rotating palm grip to control the plunger; the pressure gauge is to measure pressure and the extension tube is to connect catheters. The angle of the pressure gauge can be re-adjusted during the procedure.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

Performance testing was conducted to validate and verify that the proposed device met all design specifications and was found to be substantially equivalent to the predicate device:

Biocompatibility Testing:
Pyrogen Test
Endotoxin Test
Acute Systemic Toxicity Test
Irritation Test
Cytotoxicity Test
Skin sensitization Test
Haemolysis Study
Complement Activity Test
Thrombosis test

Package Penetrate Testing
Asepsis Testing
Aging Testing
EtO and ECH Residue Testing

Bench Testing

Appearance test

Positive pressure sealing

Negative pressure sealing

Male luer lock testing

Capacity scale

Gauge accuracy

Comparison to predicates:

ITEM	Predicate Device	Predicate Device	Predicate Device	Proposed Device
K Number	K130566	K993341	K032840	---
Device name	basixTOUCH™	IntelliSystem II Angioplasty Inflation Device	QL® Inflation Device	Balloon in-deflation device
Manufacturer	Merit Medical Systems, Inc.	Merit Medical Systems, Inc.	Atrion Medical Products, Inc.	Beijing Demax Medical Technology Co., Ltd
Classification	II	II	II	II
Product Code	MAV	MAV	KOE and MAV	MAV
Regulation Number	870.1650	870.1650	876.5520 and 870.1650	870.1650
Intended Use	The basixTOUCH inflation syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the	The Merit Medical Intellisystem II Monitor is for use only with the disposable In Intellisystem25 syringe. It may be used to monitor the pressure of interventional devices as well as measure	The Inflation Device is recommended for use with balloon dilatation catheters to create and monitor the pressure in the balloon and to deflate the balloon.	The Balloon In-deflation device is used for the inflation and deflation of a balloon dilatation catheter, to dilate the vessel or

	pressure within the balloon.	injectate pressure in various areas of the body.		implant a stent.
Volume	30ml	20ml	10, 14, 20, 25, 40, 60 ml	20ml, 30ml
Range of positive pressure	Zero to +35ATM	Zero to +35ATM	15, 30, 40 ATM	Zero to +30ATM
Lock mechanism	Thread lock mechanism	Thread lock mechanism	Thread lock mechanism	Thread lock mechanism
Plunger	Unknown	Unknown	Screw-type plunger	Screw-type plunger
Volume dispensed	Unknown	0.45ml ±0.07ml per 360º handle rotation	Unknown	Syringe with capacity 20ml: 0.43ml per 360º handle rotation Syringe with capacity 30ml:0.76ml per 360º handle rotation
Accuracy	±2.5% full scale typical (±0.9 ATM/Bar)	±2.5% full scale typical (±0.5 ATM/Bar)	Between ±0.5 ATM/Bar and ±0.6 ATM/Bar	±4.0% full scale typical (between ±0.8 and ±1 ATM/Bar)
Barrel material	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate
Handle/plunger material	ABS	ABS	Glass filled nylon 6/6 / Teflon	PA66+30% Fiberglass
Extension tubing	Unknown	Unknown	Polyurethane	Polyurethane
Gauge	Unknown	Unknown	EPDM; brass and stainless steel	Brass and PC
Connector	Male, rotating	Male, rotating	Male, rotating	Male, rotating
Mechanism of quick release handle	Yes	No	No	No
Display function	No	Yes	No	No

Biocompatibility	No Cytoxicity	No Cytoxicity	Unknown	No Cytoxicity
	No Evidence of Dermal	No Evidence of Dermal		No Evidence of Dermal
	No-Evidence of Intracutaneous Reactivity	No-Evidence of Intracutaneous Reactivity		No-Evidence of Intracutaneous Reactivity
Sterilization	ETO	ETO	ETO	ETO
SAL	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Sterilization Validation	Per ISO 11135-1:2006	Per ISO 11135-1	ISO 11135-1	Per ISO 11135-1:2006
Labeling	Complies with FDA Requirements			
Sterilization Package Performance	Complies with ISO 11607-1:2006			
Package's material	Unknown	Unknown	Unknown	PETG and Tyvek

Summary of Clinical Tests:

The proposed device of this premarket submission, Balloon In-deflation Device, does not require clinical studies to support substantial equivalence.

Conclusion:

The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are as safe and as effective and performs as well as the predicate device. Balloon In-deflation Device can be claimed to be Substantially Equivalent (SE) to the predicate device, namely, the basixTouch inflation device cleared in K130566, IntelliSystem II Angioplasty Inflation Device cleared in K993341and the QL® inflation device cleared in K032840.