



Food and Drug Administration
10903 New Hampshire Avenue
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May 28, 2015

Texas Medical Technologies, Inc.
% Ms. Viviana Gonzalez
Consultant
Pomamed Consulting LLC
PO Box 9818
San Juan, PR 00908-0818

Re: K142954
Trade/Device Name: PTA 14 Balloon Dilatation Catheter OTW
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 8, 2015
Received: May 8, 2015

Dear Ms. Gonzalez:

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" (21CFR 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142954

Device Name

PTA 14 Balloon Dilatation Catheter OTW

Indications for Use (Describe)

The PTA 14 Balloon Dilatation Catheter OTW is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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.

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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.”

1 – Company Information & Contact Person

Company Name: Texas Medical Technologies, Inc.
Company Address: 9005 Montana Ave., Suite A
El Paso, TX 79925

Telephone: (915) 774-4321
Fax: (915) 774-4323
Contact Person: Cesar Rios, Quality Assurance & Regulatory Manager
Date Prepared: 4/28/2015

2 – Device Name & Classification

Proprietary Name: PTA 14 Balloon Dilatation Catheter OTW
Common Name: Percutaneous Transluminal Angioplasty Catheter
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Product Code: LIT
Device Class: II

3 – Predicate Devices

Legally Marketed Substantially Equivalent Predicate Devices

Proprietary Name: Amphirion Deep 0.014” OTW PTA Balloon Catheter
Company Name: Invatec Innovative Technologies, s.r.l.
Common Name: Catheter
Classification Name: Diagnostic Intravascular Catheter
Regulation Number: 21 CFR 870.1250
Product Code: LIT
Device Class: II
Primary Predicate
510(k) Number: K042624
Secondary Predicate
510k Number: K050073, K052791

4 – Device Description

The PTA 14 Balloon Dilatation Catheter OTW is a 0.014” Over-The-Wire (OTW) PTA Balloon Dilatation Catheter with a semi-compliant inflatable balloon mounted on the distal end of the catheter. It is designed for carrying out percutaneous transluminal angioplasty (PTA) in the peripheral vessels. The balloon catheter has a coaxial shaft design. The outer lumen is used for balloon inflation and the inner lumen (guide wire

lumen) permits the use of a guide wire with a maximum outer diameter of 0.014 inch. The proximal segment of the catheter includes one female luer-lock port connected to the inflation lumen, and one female luer-lock for the guide wire lumen.

The PTA 14 Balloon Dilatation Catheter is compatible with a 4 Fr. introducer sheath.

The device is supplied sterile and is intended for single use.

The following table lists the models and sizes available for the PTA 14 Balloon Dilatation Catheter.

Table 4.1. PTA 14 Balloon Dilatation Catheter Models and Sizes.

Model Numbers	Usable Length (cm)	Balloon Diameter (mm)	Balloon Length (mm)
PDC14-120-2004	120	2	40
PDC14-120-2008	120	2	80
PDC14-120-2012	120	2	120
PDC14-120-2015	120	2	150
PDC14-120-2504	120	2.5	40
PDC14-120-2508	120	2.5	80
PDC14-120-2512	120	2.5	120
PDC14-120-2515	120	2.5	150
PDC14-120-3004	120	3.0	40
PDC14-120-3008	120	3.0	80
PDC14-120-3012	120	3.0	120
PDC14-120-3015	120	3.0	150
PDC14-120-3504	120	3.5	40
PDC14-120-3508	120	3.5	80
PDC14-120-3512	120	3.5	120
PDC14-120-3515	120	3.5	150
PDC14-120-4004	120	4.0	40
PDC14-120-4008	120	4.0	80
PDC14-120-4012	120	4.0	120
PDC14-120-4015	120	4.0	150
PDC14-150-2004	150	2	40
PDC14-150-2008	150	2	80
PDC14-150-2012	150	2	120
PDC14-150-2015	150	2	150
PDC14-150-2504	150	2.5	40
PDC14-150-2508	150	2.5	80
PDC14-150-2512	150	2.5	120
PDC14-150-2515	150	2.5	150
PDC14-150-3004	150	3.0	40
PDC14-150-3008	150	3.0	80
PDC14-150-3012	150	3.0	120
PDC14-150-3015	150	3.0	150
PDC14-150-3504	150	3.5	40
PDC14-150-3508	150	3.5	80
PDC14-150-3512	150	3.5	120
PDC14-150-3515	150	3.5	150
PDC14-150-4004	150	4.0	40
PDC14-150-4008	150	4.0	80
PDC14-150-4012	150	4.0	120
PDC14-150-4015	150	4.0	150

5 – Indications for Use

The PTA 14 Balloon Dilatation Catheter OTW is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

6 – Summary of Technological Characteristics Comparison

The PTA 14 Balloon Dilatation Catheter OTW is similar to the predicate device with respect to intended use and fundamental design characteristics such as principle of operation, components, materials, and dimensions. Furthermore, the PTA14 Balloon Dilatation Catheter OTW performs similarly to the predicate device and passed the predetermined acceptance criteria for mechanical and biocompatibility testing. Therefore, the PTA 14 Balloon Dilatation Catheter OTW is substantially equivalent to the predicate device.

7 – Testing Summary

The following bench tests were performed to evaluate the design elements and performance characteristics of the PTA 14 Balloon Dilatation Catheter OTW and to demonstrate substantial equivalence to the predicate devices. The PTA 14 Balloon Dilatation Catheter OTW met the predetermined acceptance criteria. Testing was performed on unaged and aged devices. Tests results show that the PTA 14 Balloon Dilatation Catheter OTW is substantially equivalent to the predicate devices.

7.1- Bench Testing Table

Table 7.1.1 below provides a summary of the bench testing performed on the PTA 14 Balloon Dilatation Catheter OTW.

Table 7.1.1. Bench Testing Performed on the PTA 14 Balloon Dilatation Catheter OTW.

Test #	Test Name	Applicable Standard or Internal Test Method	Test Results
1	Dimensional Analysis	Internal Test Method	T=0 Pass T=2 Pass
2	Trackability	Internal Test Method	T=0 Pass T=2 Pass
3	Kink Resistance	Internal Test Method	T=0 Pass T=2 Pass
4	Balloon Performance	Internal Test Method	T=0 Pass T=2 Pass
5	Balloon Fatigue and Leakage	Internal Test Method	T=0 Pass T=2 Pass
6	Balloon Burst Pressure	Internal Test Method	T=0 Pass T=2 Pass
7	Shaft Burst Pressure	Internal Test Method	T=0 Pass T=2 Pass
8	Catheter Joint Strength	Internal Test Method	T=0 Pass T=2 Pass
9	Hub Durability and Compatibility	ISO 594-1, ISO 594-2,	T=0 Pass

		and Internal Test Method	T=2 Pass
10	Torque Strength	FDA Guidance 1608	T=0 Pass RT=5 Pass
11	Coating Durability	Internal Test Method	T=0 Pass T=2 Pass
12	Coating Integrity	Internal Test Method	T=0 Pass T=2 Pass
13	Radiopacity	Internal Test Method	T=0 Pass T=2 Pass
14	Corrosion Resistance	Internal Test Method	T=0 Pass T=2 Pass
15	Packaging Integrity	ASTM F88-09, ASTM F1929-98, ASTM D 4169-05	T=0 Pass T=2 Pass
16	Sterilization Validation	ISO 11135-1	T=0 Pass T=2 Pass

7.2 – Biocompatibility

The PTA 14 Balloon Dilatation Catheter OTW is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤ 24 hours). Biocompatibility testing was performed in accordance with ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process” (2009). Table 7.2.1 below describes the testing performed to determine biocompatibility. All testing met the predetermined acceptance criteria.

Table 7.2.1. Summary of Biocompatibility Testing for the PTA 14 Balloon Dilatation Catheter OTW.

Test Name	Test Description
Cytotoxicity - Test	Cytotoxicity – MEM Elution Test (ISO 10993-5:1999)
	Cytotoxicity – MTT Quantitative Evaluation (ISO 10993-5:2009)
Sensitization - Test	Murine Local Lymph Node Assay (LLNA) (ASTM F2148)
Irritation - Test	Intracutaneous Study (ISO 10993-10:2002)
Systemic Toxicity - Test	Acute Systemic Toxicity Test (ISO 10993-11:2006)
Hemocompatibility Test	Hemolysis (ASTM F756-00 and ISO 10993-4:2002)
Hemocompatibility – Test	Partial Thromboplastin Time (ASTM F 2382 and ISO 10993-4:2002)
Complement Activation - Test	Complement Activation C3a and SC5b-9 (ISO 10993-4:2002, 2006)
In vivo Thrombogenicity - Test	Four Hour Thromboresistance Evaluation in Dogs (ISO 10993-4:2002, 2006)
Pyrogenicity – Test	Pyrogen (USP 30 NF 25 and ISO 10993-11:2006)

8 – Sterilization Testing Summary

Validation Sterilization Process	Sterility Assurance Level (SAL)	Validation Result
Ethylene Oxide Gas	10^{-6}	Pass

9 – Conclusion

The PTA 14 Balloon Dilatation Catheter OTW is substantially equivalent in intended use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging to the predicate devices. Differences between the devices do not raise any new issues of safety or effectiveness.