DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 12, 2016

Texas Medical Technologies, Inc.
% EJ Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K153703
Trade/Device Name: Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 12, 2016
Received: April 12, 2016

Dear EJ Smith:

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)*
K153703

Device Name
Guiding Catheter

Indications for Use *(Describe)*
The Guiding Catheter is intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vasculature.

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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Section 5: 510(k) Summary

5.1 – Company Information & Contact Person

Company Name:	Texas Medical Technologies Inc.
Company Address:	9005 Montana Ave. Ste. A El Paso, Texas 79925
Telephone:	(915) 774-4321
Fax:	(915) 774-4323
Contact Person:	Cesar Rios, Quality Assurance & Regulatory Manager
Date Prepared:	4/11/2016

5.2 – Device Name & Classification

Proprietary Name:	Guiding Catheter
Common Name:	Catheter
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Device Class:	II

5.3 – Predicate Device

Legally Marketed Substantially Equivalent Predicate Device

Proprietary Name:	Vista Brite Tip
Company Name:	Cordis Corporation
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Device Class:	II
510(k) Number	K972978

5.4 – Device Description

The TXM Guiding Catheter is a guiding catheter, for application in intravascular vessels. It consists of a lubricous inner liner made from Teflon, a stainless steel braid over the inner liner. The outer shaft consists of durometer hardness and different lengths of colored Polyether block amide. A Polycarbonate hub is attached to the proximal end of the Guiding Catheter. A strain relief is placed at the proximal end of the Guiding Catheter and over the distal end of the hub. The device shafts will have an outer diameter of 5 French sizes (0.070”) and 6 French sizes (0.082) respectively for each catheter. The 5 French sizes will have an inner diameter of 0.058” and the 6

French sizes will have an inner diameter of 0.070". The device is available in length of 100cm. The device is supplied sterile and is intended for single use.

The device is supplied sterile and is intended for single use

The following table lists the models and sizes available for Guiding Catheter.

Table 5.4.1. Guiding Catheter Models and Sizes

Commercial Model Number	French size	Shaft Length (cm)	Outer Diameter (inches)	Inner Diameter (inches)	Marker Band Material	Tip Shape
GC-510-JL35	5	100	0.070	0.058	Tungsten	JL 3.5
GC-510-JL40	5	100	0.070	0.058	Tungsten	JL 4
GC-510-JL45	5	100	0.070	0.058	Tungsten	JL 4.5
GC-510-JL50	5	100	0.070	0.058	Tungsten	JL 5
GC-510-JL60	5	100	0.070	0.058	Tungsten	JL 6
GC-510-JR35	5	100	0.070	0.058	Tungsten	AL 1
GC-510-JR40	5	100	0.070	0.058	Tungsten	AL 2
GC-510-JR50	5	100	0.070	0.058	Tungsten	AL 3
GC-510-JR60	5	100	0.070	0.058	Tungsten	JR 3.5
GC-510-AL10	5	100	0.070	0.058	Tungsten	JR 4
GC-510-AL20	5	100	0.070	0.058	Tungsten	JR 5
GC-510-AL30	5	100	0.070	0.058	Tungsten	JR 6
GC-510-AR10	5	100	0.070	0.058	Tungsten	AR 1
GC-510-AR20	5	100	0.070	0.058	Tungsten	AR 2
GC-510-AR30	5	100	0.070	0.058	Tungsten	AR 3
GC-510-MPA1	5	100	0.070	0.058	Tungsten	MPA 1
GC-510-MPA1	5	100	0.070	0.058	Tungsten	MPA 2
GC-510-MPB1	5	100	0.070	0.058	Tungsten	MPB 1
GC-510-MPB2	5	100	0.070	0.058	Tungsten	MPB 2
GC-610-JL35	6	100	0.082	0.070	Tungsten	JL 3.5
GC-610-JL40	6	100	0.082	0.070	Tungsten	JL 4
GC-610-JL45	6	100	0.082	0.070	Tungsten	JL 4.5
GC-610-JL50	6	100	0.082	0.070	Tungsten	JL 5
GC-610-JL60	6	100	0.082	0.070	Tungsten	JL 6
GC-610-JR35	6	100	0.082	0.070	Tungsten	AL 1
GC-610-JR40	6	100	0.082	0.070	Tungsten	AL 2
GC-610-JR50	6	100	0.082	0.070	Tungsten	AL 3
GC-610-JR60	6	100	0.082	0.070	Tungsten	JR 3.5
GC-610-AL10	6	100	0.082	0.070	Tungsten	JR 4
GC-610-AL20	6	100	0.082	0.070	Tungsten	JR 5
GC-610-AL30	6	100	0.082	0.070	Tungsten	JR 6
GC-610-AR10	6	100	0.082	0.070	Tungsten	AR 1
GC-610-AR20	6	100	0.082	0.070	Tungsten	AR 2
GC-610-AR30	6	100	0.082	0.070	Tungsten	AR 3
GC-610-MPA1	6	100	0.082	0.070	Tungsten	MPA 1
GC-610-MPA1	6	100	0.082	0.070	Tungsten	MPA 2
GC-610-MPB1	6	100	0.082	0.070	Tungsten	MPB 1
GC-610-MPB2	6	100	0.082	0.070	Tungsten	MPB 2

5.5 – Indications for Use

The guiding catheter is intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vasculature.

The Indications for Use are identical, the devices are both intended for intravascular use and the Indications for Use do not change the intended use of the TXM Guiding Catheter when compared to the predicate device.

5.6 – Summary of Technological Characteristics Comparison

Based on a comparison of the indications for use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging, it is determined that the Guiding Catheter is substantially equivalent to the predicate device. Table 5.6 below provides a comparison of the Guiding Catheter and the predicate.

Table 5.6.1 Comparison of the Guiding Catheter and the Predicate Device.

Technical Characteristics / Principle of Operation	TXM Guiding Catheter	Vista Brite Guiding Catheter	Substantially Equivalent?
Length	100 cm	90 cm, 100 cm, 110 cm, 125 cm	Yes
Outer Diameter	0.070”- 0.082”	0.068”- 0.082”	Yes
Inner Diameter	0.058”- 0.070”	0.056”- 0.070”	Yes
Shape	Judkins right, Judkins left, Amplatz right, Amplatz left and Multipurpose.	Judkins right, Judkins left, Amplatz right, Amplatz left and Multipurpose and others.	Yes
Inner Liner Material	Polytetrafluoroethylene (PTFE)*	Polytetrafluoroethylene (PTFE)	Yes
Braid Reinforcement Material	Stainless Steel*	Stainless Steel	Yes
Radiopaque Marker	Tungsten Material*	Radiopaque filler	Yes
Outer Shaft Material	Nylon, Pebax, Polyurethane*	Nylon	Yes
Luer Material	Polycarbonate*	Unknown	Yes
Luer Connector	Female Luer Connector*	Female Luer Connector	Yes
Anatomical Site Use	Peripheral, Coronary	Peripheral, Coronary	Yes
Delivery to Site	Over-the-wire	Over-the-wire	Yes
Guidewire Compatibility	Maximum 0.038”	Maximum 0.038”	Yes
Packaging	Tyvek Pouch	Tyvek Pouch	Yes
Sterilization	EtO Gas	EtO Gas	Yes

* Denotes a patient-contacting material.

5.7 – Testing Summary

The following bench tests were performed to evaluate the design elements and performance characteristics of the Guiding Catheter and to demonstrate substantial equivalence to the predicate device. The Guiding Catheter met the predetermined acceptance criteria. Testing was performed on non-aged devices (T=0) as well as on devices subject to 3 years of accelerated aging (T=3). Tests results show that the Guiding Catheter is substantially equivalent to the predicate device.

5.7.1- Bench Testing Table

Table 5.7.1 below provides a summary of the bench testing performed on the Guiding Catheter.

Table 5.7.1. Bench Testing Performed on Guiding Catheter

Test #	Test Name	Applicable Standard or Internal Test Method	Test Results (T=3)		Test #	Test Name	Applicable Standard or Internal Test Method	Test Results (T=3)
1	Air Leak	ISO 10555	T=0;T=3 Pass		12	Corrosion Resistance	ISO 10555	T=0;T=3 Pass
2	In-Vitro Track Force	Internal Test Method	T=0;T=3 Pass		13	Radiopacity	ASTM-F640-12	T=0;T=3 Pass
3	Stiffness	Internal Test Method	T=0;T=3 Pass		14	Torque Response	Internal Test Method	T=0;T=3 Pass
4	Tensile Strength	ISO 10555	T=0;T=3 Pass		15	Torque to Failure	Internal Test Method	T=0;T=3 Pass
5	Gravity Flow Rate	ISO 10555	T=0;T=3 Pass		16	Ovalization	Internal Test Method	T=0;T=3 Pass
6	Liquid Leak	ISO 10555	T=0;T=3 Pass		17	Simulated Use	Internal Test Method	T=0;T=3 Pass
7	Power Injector (Static Burst Pressure)	ISO 10555	T=0;T=3 Pass		18	Seal Strength (Pouch)	ASTM F88/F88M-09	T=0;T=3 Pass
8	Tip Shape Retention	Internal Test Method	T=0;T=3 Pass		19	Dye Penetration Test	ASTM-F1929-12	T=0;T=3 Pass
9	Dimensional & Physical Attributes	ISO 10555	T=0;T=3 Pass		20	Female Luer Verification	ISO 594	T=0;T=3 Pass
10	Kink Testing	Internal Test Method	T=0;T=3 Pass		21	Shipping and Transportation	ISTA 3A	T=0;T=3 Pass
11	Buckling Test	Internal Test Method	T=0;T=3 Pass		22	Accelerated Aging	ASTM F1980-07	T=0;T=3 Pass

5.7.2 – Biocompatibility

The Guiding Catheter 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 5.7.2 below describes the testing performed to determine biocompatibility. All testing met the predetermined acceptance criteria.

Table 5.7.2. Summary of Biocompatibility Testing for the Guiding Catheter

Biological Effect	Test	Compliance Standard
Cytotoxicity	L929 Neutral Red Uptake (NRU) - ISO	ISO10993-5
Irritation	Intracutaneous Injection - ISO	ISO10993-10
Sensitization	Kligman Maximization Murine Local Lymph Assay	ISO10993-10
Systemic Toxicity	ISO Acute Systemic Toxicity Test	ISO10993-11
Pyrogenicity	Pyrogen Test in Rabbit	USP<151> ISO10993-11
	Limulus Amebocyte Lysate	USP <85> 38, NF 33, 2015
Hemocompatibility	Hemolysis-Complete (Direct and Indirect)	ISO10993-4
	Complement Activation	ISO10993-4
	In-Vivo Thrombogenicity	ISO10993-4
Toxicological Hazard	Risk Assessment of Extractables and Leachables	ISO 10993-17

5.8 - Sterilization Testing Summary

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

5.9 – Conclusion

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