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

September 13, 2016

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

Re: K153771
Trade/Device Name: TXM Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 7, 2016
Received: September 7, 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)*
K153771

Device Name
TXM Guiding Sheath

Indications for Use *(Describe)*
The Guiding Sheath Introducer is intended for use in the hospital catheterization laboratory for the percutaneous introduction of various devices into veins and/or arteries in a variety of diagnostic and therapeutic procedures.

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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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:	09/08/2016

5.2 – Device Name & Classification

Proprietary Name:	TXM Guiding Sheath
Common Name:	Catheter introducer
Classification Name:	Catheter introducer
Regulation Number:	21 CFR 870.1340
Product Code:	DYB
Device Class:	II

5.3 – Predicate Device

Legally Marketed Substantially Equivalent Predicate Device

Proprietary Name:	Arrow Fischell Kink Resistance Percutaneous Sheath Introducer Set
Company Name:	Arrow International Inc.
Common Name:	Catheter introducer
Classification Name:	Catheter introducer
Regulation Number:	21 CFR 870.1340
Product Code:	DYB
Device Class:	II
510(k) Number	K924607

5.4 – Device Description

The Guiding Sheath is intended for intravascular use for the introduction of interventional/diagnostic devices to the human vasculature. The Guiding Sheath is designed to work as a vessel introducer and a guiding catheter. It consists of a lubricous inner liner made from Teflon, and a stainless steel coil over the inner liner. The outer shaft consists of colored Polyether block amide. A Radiopaque Marker band is attached to the distal end of the shaft for radiopacity. The Distal end of the shaft is atraumatic. The Proximal end of the catheter is attached to a Hemostatic Valve. The device is available in

three inner diameter sizes of 4Fr, 5Fr, and 6Fr; consisting of 0.063", 0.076" and 0.087" (throughout the shaft) respectably. A lubricious hydrophilic coating shall be applied to the outer diameter of the Catheter Sheath for improved trackability through the vasculature. The device contains a separate Dilator shaft made of two different materials depending on the size. For the 4Fr, Grilamid is used for the body and the Luer attached to the proximal end as well. For the 5Fr and 6F, high densiy polyethylene (HDPE) is used for the body and the Luer attached to the proximal end as well. The distal end of the Dilator is tapered for ease of access to the vessel. The device is available in lengths of 45cm and 90cm.

The device is supplied sterile and is intended for single use

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

Table 5.4.1. TXM Guiding Sheath Models and Sizes

Commercial Model Number	French size	Shaft Length (cm)	Inner Diameter (inches)	Marker Band Material	Hemostatic Valve
GS-445-CS	4	45	0.063	Platinum-Iridium	Cross Cut
GS-445-TS	4	45	0.063	Platinum-Iridium	Tuohy Borst
GS-490-CS	4	90	0.063	Platinum-Iridium	Cross Cut
GS-490-TS	4	90	0.063	Platinum-Iridium	Tuohy Borst
GS-545-CS	5	45	0.076	Platinum-Iridium	Cross Cut
GS-545-TS	5	45	0.076	Platinum-Iridium	Tuohy Borst
GS-590-CS	5	90	0.076	Platinum-Iridium	Cross Cut
GS-590-TS	5	90	0.076	Platinum-Iridium	Tuohy Borst
GS-645-CS	6	45	0.087	Platinum-Iridium	Cross Cut
GS-645-TS	6	45	0.087	Platinum-Iridium	Tuohy Borst
GS-690-CS	6	90	0.087	Platinum-Iridium	Cross Cut
GS-690-TS	6	90	0.087	Platinum-Iridium	Tuohy Borst

5.5 – Indications for Use

The Guiding Sheath Introducer is intended for use in the hospital catheterization laboratory for the percutaneous introduction of various devices into veins and/or arteries in a variety of diagnostic and therapeutic procedures.

5.5.1 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 Sheath 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 TXM Guiding Sheath is substantially equivalent to the predicate device.

Table 5.6 below provides a comparison of the TXM Guiding Sheath and the predicate.

Table 5.6.1 Comparison of the TXM Guiding Sheath and the Predicate Device.

Technical Characteristics / Principle of Operation	**TXM Guiding Sheath**	Super Arrow Flex® Percutaneous Sheath Introducer Set	**Substantially Equivalent?**
Sheath Length	45 cm - 90 cm	11 cm, 24 cm, 45 cm, 65 cm, 90 cm	Yes
Sheath Size	4 Fr, 5 Fr and 6 Fr	5 Fr, 6 Fr, 7 Fr, 8 Fr, 9 Fr, 10 Fr	Yes
Shape	Straight	Straight	Yes
Inner Liner Material	Polytetrafluoroethylene (PTFE)	Unknown	Yes
Wire Reinforcement Material	Stainless Steel	Stainless Steel	Yes
Radiopaque Marker	Platinum/Iridium marker band	Radiopaque marker band	Yes
Outer Shaft Material	Polyeter Block Amide	Polyurethane	Yes
Luer Material	Polycarbonate	Not Applicable	Yes
Cross Cut Valve with three way stopcock	Polycarbonate/Silicon Valve	Unknown	Yes
Touhy Borst Adapeter with side arm extension	Polycarbonate, Polyurethane	Unknown	Yes
Luer Connector	Female Luer Connector	Female Luer Connector	Yes
Hydrophilic Coated	Yes*	Yes	Yes
Anatomical Site Use	Percutaneous access	Percutaneous access	Yes
Delivery to Site	Over dilator and Over the wire	Over dilator and Over the	Yes
Dilator	HDPE and Nylon	Polymer	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 TXM Guiding Sheath and to demonstrate substantial equivalence to the predicate device. The TXM Guiding Sheath met the predetermined acceptance criteria. Testing was performed on non-aged devices (T=0) as well as on devices subject to 2 years of accelerated aging (T=2). Tests results show that the TXM Guiding Sheath 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 TXM Guiding Sheath.

Table 5.7.1. Bench Testing Performed on TXM Guiding Sheath.

Test #	Test Name	Applicable Standard or Internal Test Method	Test Results (T=2)		Test #	Test Name	Applicable Standard or Internal Test Method	Test Results (T=2)
1	Dimensional & Physical Attributes	ISO 10555	T=0;T=2 Pass		9	In-Vitro Track Force	Internal Test Method	T=0;T=2 Pass
2	Lubricity of Hydrophilic Coating	Internal Test Method	T=0;T=2 Pass		10	Kink Resistance	Internal Test Method	T=0;T=2 Pass
3	Dilator Guidewire and Sheath Catheter Compatibility	Internal Test Method	T=0;T=2 Pass		11	Durability of Hydrophilic Coating	Internal Test Method	T=0;T=2 Pass
4	Liquid Leak	ISO 10555	T=0;T=2 Pass		12	Tensile Strength	ISO 10555	T=0;T=2 Pass
5	Air Leak	ISO 10555	T=0;T=2 Pass		13	Coating Integrity	Internal Test Method	T=0;T=2 Pass
6	Seal Strength (Pouch)	ASTM F88/F88M-09	T=0;T=2 Pass		14	Corrosion Resistance	ISO 10555	T=0;T=2 Pass
7	Dye Penetration Test	ASTM-F1929-12	T=0;T=2 Pass		15	Female Luer Verification	ISO 594	T=0;T=2 Pass
8	Radiopacity	ASTM-F640-12	T=0;T=2 Pass		16	Accelerated Aging	ASTM F1980-07	T=0;T=2 Pass

5.7.2 – Biocompatibility

The TXM Guiding Sheath 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 TXM Guiding Sheath.

Biological Effect	Test	Compliance Standard
Irritation	Intracutaneous Injection - ISO	ISO10993-10
Sensitization	Kligman Maximization Murine Local Lymph Assay	ISO10993-10
Systemic Toxicity	ISO Acute Systemic Toxicity Test	ISO10993-11
Cytotoxicity	L929 Neutral Red Uptake Cytotoxicity Test	ISO 10993-5
Pyrogenicity	Pyrogen Test in Rabbit	USP<151> ISO10993-11
Hemocompatibility	Hemolysis-Complete (Direct and Indirect)	ISO10993-4
	Complement Activation	ISO10993-4
	In-Vivo Thrombogenicity	ISO10993-4

5.8 - Sterilization Testing Summary

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

5.9 – Conclusion

The TXM Guiding Sheath 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.