November 21, 2017

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

Re: K170915
Trade/Device Name: TXM Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 13, 2017
Received: October 16, 2017

Dear Mr. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth J. Cavanaugh -S

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)*
K170915

Device Name
TXM Hydrophilic Guidewire

Indications for Use *(Describe)*
To facilitate the placement of devices during diagnostic or interventional 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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"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

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:	02/28/2017

5.2 – Device Name & Classification

Proprietary Name:	TXM Hydrophilic Guidewire
Common Name:	Catheter guide wire
Classification Name:	Wire, Guide, Catheter
Regulation Number:	21 CFR 870.1330
Product Code:	DQX
Device Class:	II

5.3 – Predicate Device

Legally Marketed Substantially Equivalent Predicate Device

Proprietary Name:	Hydrophilic Coated Guidewire
Company Name:	Lake Region Medical
Common Name:	Guides, guidewires, or spring guidewires
Classification Name:	Wire, Guide, Catheter
Regulation Number:	21 CFR 870.1330
Product Code:	DQX
Device Class:	II
510(k) Number	K133155

5.4 – Device Description

The TXM Hydrophilic Guidewire is a hydrophilic coated device which is constructed with a nitinol inner core which is covered with a polyurethane outer layer coated with a lubricious coating to minimize friction during use. The TXM Hydrophilic Guidewire outer diameter is 0.035" and is available in a variety of lengths ranging from 80 cm to 260 cm. The TXM Hydrophilic Guidewire is also constructed in stiff and standard shaft configuration with straight or angled distal tip. The device is supplied sterile and is intended for single use only.

The following table lists the models and sizes available for TXM Hydrophilic Guidewire.

Table 5.4 TXM Hydrophilic Guidewire Models and Sizes

Product Code	Outer Diameter (inches)		Length (cm)	Shaft Configuration	Tip Shape
	Shaft	Tip			
HGW-35080-FS	0.0335”	0.0305”	80	Standard	Straight
HGW-35150-FS	0.0335”	0.0305”	150	Standard	Straight
HGW-35180-FS	0.0335”	0.0305”	180	Standard	Straight
HGW-35260-FS	0.0335”	0.0305”	260	Standard	Straight
HGW-35080-FA	0.0335”	0.0305”	80	Standard	Angled
HGW-35150-FA	0.0335”	0.0305”	150	Standard	Angled
HGW-35180-FA	0.0335”	0.0305”	180	Standard	Angled
HGW-35260-FA	0.0335”	0.0305”	260	Standard	Angled
HGW-35080-SS	0.0335”	0.0305”	80	Stiff	Straight
HGW-35150-SS	0.0335”	0.0305”	150	Stiff	Straight
HGW-35180-SS	0.0335”	0.0305”	180	Stiff	Straight
HGW-35260-SS	0.0335”	0.0305”	260	Stiff	Straight
HGW-35080-SA	0.0335”	0.0305”	80	Stiff	Angled
HGW-35150-SA	0.0335”	0.0305”	150	Stiff	Angled
HGW-35180-SA	0.0335”	0.0305”	180	Stiff	Angled
HGW-35260-SA	0.0335”	0.0305”	260	Stiff	Angled

5.5 – Indications for Use

To facilitate the placement of devices used during diagnostic and interventional procedures.

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 Hydrophilic Guidewire 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 Hydrophilic Guidewire is substantially equivalent to the predicate device. Table 5.6 below provides a comparison of the TXM Hydrophilic Guidewire and the predicate.

Table 5.6 Comparison of the TXM Hydrophilic Guidewire and the Predicate Device

Technical Characteristics / Principle of Operation	TXM Hydrophilic Guidewire	Hydrophilic Coated Guidewire	Substantially Equivalent?
Length	80cm-260cm	80cm-260cm	Yes
Outer Diameter	0.035”	0.035”	Yes
Shape	Straight or Angled	Straight or Angled	Yes
Shaft Configuration	Standard or Stiff	Standard or Stiff	Yes
Inner Core Material	Nitinol	Nitinol	Yes
Outer Jacket Material	Polyurethane, Tungsten	Polyurethane, Radiopaque material unknown	Yes
Hydrophilic Coated	Yes*	Yes	Yes
Anatomical Site Use	Peripheral Vascular System	Peripheral Vascular System	Yes
Delivery to Site	Through Introducer Sheath	Through Introducer Sheath	
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 Hydrophilic Guidewire and to demonstrate substantial equivalence to the predicate device. The TXM Hydrophilic Guidewire 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 Hydrophilic Guidewire 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 Hydrophilic Guidewire.

Table 5.7.1 Bench Testing Performed on TXM Hydrophilic Guidewire

Test No.	Test Name	Applicable Standard or Internal Test Method	Test Results	
1	Dimensional and Physical Attributes	ISO 11070:2014	T=0 T=2	Pass
2	Torque Strength	FDA Coronary and Cerebrovascular Guidewire Guidance / Internal Test Method	T=0 T=2	Pass
3	Torqueability	FDA Coronary and Cerebrovascular Guidewire Guidance / Internal Test Method	T=0 T=2	Pass
4	Guidewire compatibility	FDA Coronary and Cerebrovascular Guidewire Guidance / Internal Test Method	T=0 T=2	Pass
5	Radiopacity	ASTM-F640-12	T=0 T=2	Pass
6	Tensile Strength	FDA Coronary and Cerebrovascular Guidewire Guidance / ISO 11070:2014	T=0 T=2	Pass
7	Coating Adherence and Integrity; Particulate Quantitation	FDA Coronary and Cerebrovascular Guidewire Guidance / Internal Test Method	T=0 T=2	Pass
8	Durability of Hydrophilic Coating	Internal Test Method	T=0 T=2	Pass
9	Lubricity of Hydrophilic Coating	Internal Test Method	T=0 T=2	Pass
10	Shaft stiffness and Tip Flexibility	FDA Coronary and Cerebrovascular Guidewire Guidance / ASTM D747-10	T=0 T=2	Pass
11	Fracture	ISO 11070:2014	T=0 T=2	Pass
12	Tip Impact	FDA Coronary and Cerebrovascular Guidewire Guidance / Internal Test Method	T=0 T=2	Pass
13	Corrosion Resistance	ISO 11070:2014	T=0 T=2	Pass
14	Trackability	Internal Test Method	T=0 T=2	Pass
15	Packing Dye Penetration	ASTM F1929–15/F1886-09	T=0 T=2	Pass
16	Seal Strength	ASTM F88 / F88M - 15	T=0 T=2	Pass
17	Shipping and Transit	ISTA 3A	T=0 T=2	Pass
18	Accelerated Aging	ASTM-F1980-07	Pass	

5.7.2 – Biocompatibility

The TXM Hydrophilic Guidewire 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.

Table 5.7.2 Biocompatibility Testing for the TXM Hydrophilic Guidewire

Biological Effect	Test	Compliance Standard
Cytotoxicity	L929 MEM Elution 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
Material Mediated Pyrogenicity	Pyrogen Test in Rabbit	USP<151> ISO10993-11
	Limulus Amebocyte Lysate	USP 38, NF 33, 2015
Hemocompatibility	Hemolysis-Complete (Direct and Indirect)	ISO10993-4
	Complement Activation	ISO10993-4
	In-Vivo Thrombogenicity	ISO10993-4

5.8 - Sterilization Testing Summary

Table 5.8 Sterilization Testing for the TXM Hydrophilic Guidewire

Validation Sterilization Process	Compliance Standard	Sterility Assurance Level (SAL)	Validation Result
Ethylene Oxide Gas	ISO 11135	10^{-6}	Pass

5.9 – Conclusion

The TXM Hydrophilic Guidewire 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.