DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 13, 2016

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

Re: K153125
Trade/Device Name: IntraNovo Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: December 10, 2015
Received: December 14, 2015

Dear E.J. 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,

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

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)*

Device Name
IntraNovo Microcatheter

Indications for Use *(Describe)*
The IntraNovo Microcatheter is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, and all coronary vessels. The Microcatheter is also intended for drug infusion in intra-arterial therapy and infusion of embolic materials for hemostasis. The Microcatheter should not be used in cerebral vessels.

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.

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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

Date Prepared:	10/20/2015

2. Device Name & Classification

Proprietary Name:	IntraNovo Microcatheter
Common Name:	Microcatheter
Classification Name:	Diagnostic Intravascular Catheter
Regulation Number:	21 CFR 870.1200
Product Code:	DQO
Device Class:	Class II

3. Predicate Device

Proprietary Name:	IntraNovo 25 Microcatheter
Company Name:	Texas Medical Technologies, Inc.
Common Name:	Microcatheter
Classification Name:	Diagnostic Intravascular Catheter
Regulation Number:	21 CFR 870.1200
Product Code:	DQO
Device Class:	Class II
510(k) Number:	K142817

4. Device Description

The IntraNovo Microcatheter (the "IntraNovo 21" or the "Microcatheter") is an infusion catheter intended for intravascular use. The Microcatheter consists of a single lumen. The shaft consists of a lubricous inner liner made from polytetrafluoroethylene (PTFE) with a stainless steel coil over the inner liner. The outer liner consists of different lengths of colored polyether block amide with varying durometers hardness. A lubricious hydrophilic coating covers the distal end of the IntraNovo Microcatheter. One radiopaque marker band is placed at the distal end of the Microcatheter and above the stainless steel coil. A polycarbonate hub is attached to the proximal end of the Microcatheter with a strain relief placed over the distal end of the hub.

The device shaft has an outer diameter of 2.9 French size on the proximal end and 2.4 French size on the distal end with an inner diameter of 0.021" throughout the shaft. The device is available in lengths of 110 cm and 130 cm.

The following accessories are included with the Microcatheter: a stainless steel steam shaping mandrel to allow for manual shaping of the distal tip and a 3.0 mL syringe.

Table 4.1 IntraNovo Microcatheter Models and Sizes

Design & Development Model Number	Commercial Model Number	Shaft Length (cm)	Outer Diameter		Inner Diameter	Marker Band Configuration	Tip Shape
			Distal	Proximal			
SMC-21110-1S	MC-2411-1SN	110	2.7 Fr.	2.9 Fr.	0.025"	1 Marker Band	Straight (shapeable)
SMC-21130-1S	MC-2413-1SN	130	2.7 Fr.	2.9 Fr.	0.025"	1 Marker Band	Straight (shapeable)

5. Indications for Use

   The IntraNovo Microcatheter is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, and all coronary vessels. The Microcatheter is also intended for drug infusion in intra-arterial therapy and infusion of embolic materials for hemostasis. The Microcatheter should not be used in cerebral vessels.

6. Predicate Product Comparison Table

Technical Characteristics / Principle of Operation	IntraNovo Microcatheter	IntraNovo 25 Microcatheter (Predicate)	Comments
510(k) Number		K142817	
Length	100cm - 130cm	100cm -130 cm-150cm	Same
Outer Diameter	Distal: 2.4 Fr. Proximal 2.9 Fr.	Distal: 2.7 Fr. Proximal 2.9 Fr.	Different [1] Identical
Inner Diameter	0.021"	0.025"	Different [2]
Maximum Pressure	5,171 kPa (750 psi)	5,171 kPa (750 psi)	Identical
Distal Curve	Straight (shapeable)	Straight (shapeable)	Identical
Inner Liner Material	Polytetraflouroethylene (PTFE)*	Polytetraflouroethylene (PTFE)*	Identical
Coil Reinforcement Material	Stainless Steel*	Stainless Steel*	Identical

Radiopaque Marker	Platinum/Iridium*	Platinum/Iridium*	Identical
Outer Shaft Material	Polyether Block Amide*	Polyether Block Amide*	Identical
Luer Material	Polycarbonate*	Polycarbonate*	Identical
Luer Connector	Female Luer Connector*	Female Luer Connector*	Identical
Hydrophilic Coated	Yes*	Yes*	Identical
Anatomical Site Use	Peripheral, Coronary	Peripheral, Coronary	Identical
Supplied Accessories	Shaping Mandrel, Injection Syringe	Shaping Mandrel, Injection Syringe	Identical
Delivery to Site	Over-the-wire	Over-the-wire	Identical
Guidewire Compatibility	Maximum 0.018”	Maximum 0.021”	Different [3]
Packaging	Polyethylene Hoop and Tyvek Pouch	Polyethylene Hoop and Tyvek Pouch	Identical
Sterilization	EtO Gas	EtO Gas	Identical

7. Discussion of Technological Characteristics

Both devices are equivalent with respect to their indications for use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging.

The IntraNovo Microcatheter does differ from the predicate in outer diameter of 2.4 fr versus predicate’s 2.7 fr, inner diameter of 0.021” versus the predicate’s 0.025" and guidewire compatibility of a maximum 0.018” versus the predicate’s 0.021”. The following is a discussion of why no new issues of safety and effectiveness have been raised by these differences:

1. Difference on the distal outer diameter does not impact the product performance or modifies the intended use. The smaller size is intended to reach smaller target vessels in the anatomy. The Microcatheter’s instructions for use indicate the minimum sizes of devices compatible with the Microcatheter outer diameter. This difference does not raise any new issues of safety and effectiveness.
2. Difference on the inner diameter does not impact on the product performance or modifies the intended use. The smaller size is intended to reach smaller target vessel in the anatomy. The Microcatheter’s instructions for use indicate the maximum sizes of therapeutic agents compatible with the Microcatheter inner diameter. This difference does not raise any new issues of safety and effectiveness.
3. Difference in the guidewire compatibility does not impact on the product performance or modifies the intended use. Device lumen is smaller and therefore the maximum guidewire compatible is smaller. This difference does not raise any new issues of safety and effectiveness.

8. Testing Summary

The following bench tests were performed to evaluate the design elements and performance characteristics of the IntraNovo Microcatheter and to demonstrate substantial equivalence to the predicate device. The IntraNovo Microcatheter 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 IntraNovo Microcatheter is substantially equivalent to the predicate device.

9. Bench Testing Table

Table 7.1. Bench Testing Performed on the IntraNovo Microcatheter.

Test #	Test Name	Applicable Standard or Internal Test Method	Test Results (T=0) and (T=2)
1	Guidewire & Guide Catheter Compatibility	Internal Test Method	T=0 Pass T=2 Pass
2	In-Vitro Track Force	Internal Test Method	T=0 Pass T=2 Pass
3	Durability of Hydrophilic Coating	Internal Test Method	T=0 Pass T=2 Pass
4	Lubricity of Hydrophilic Coating	Internal Test Method	T=0 Pass T=2 Pass
5	Tip Shape Retention	Internal Test Method	T=0 Pass T=2 Pass
6	Static Burst Pressure	ISO 10555	T=0 Pass T=2 Pass
7	Dimensional & Physical Attributes	ISO 10555	T=0 Pass T=2 Pass
8	Corrosion Resistance	ISO 10555	T=0 Pass T=2 Pass
9	Dynamic Burst Pressure	Internal Test Method	T=0 Pass T=2 Pass
10	Air Leak	Internal Test Method	T=0 Pass T=2 Pass
11	Liquid Leakage	Internal Test Method	T=0 Pass T=2 Pass
12	Tensile Strength	ISO 10555	T=0 Pass T=2 Pass
13	Flow Rate	Internal Test Method	T=0 Pass T=2 Pass
14	Kink Resistance	Internal Test Method	T=0 Pass T=2 Pass
15	Radiopacity	ASTM-F640-12	T=0 Pass T=2 Pass
16	Torque to Failure	Internal Test Method	T=0 Pass T=2 Pass
17	Catheter Stiffness	Internal Test Method	T=0 Pass T=2 Pass
18	Packaging Integrity	ASTM F-88-09 ASTM-1929-98	T=0 Pass T=2 Pass
19	Therapeutic Agents	Internal Test Method	T=0 Pass T=2 Pass

20	Female Luer Hub Verification	ISO 594	T=0 Pass T=2 Pass
21	Shipping and Transportation Simulation	ISTA 3PA	T=0 Pass T=2 Pass
22	Coating Integrity	Internal Test Method	T=0 Pass T=2 Pass
23	Torque Response	Internal Test Method	T=0 Pass T=2 Pass
24	Particulate Evaluation	USP <788>	T=0 Pass T=2 Pass

10. Biocompatibility

The IntraNovo Microcatheter is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24) hours.

The final sterilized device is identical to IntraNovo 25 Microcatheter (K142817) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

Biocompatibility testing was not performed since the same materials of the IntraNovo 25 Microcatheter were used and biocompatibility testing results shown that these materials are biocompatible according to ISO 10993. The IntraNovo 25 Microcatheter was cleared under 510K number K142817 on 4/23/2015.

11. Sterilization Testing Summary

Adoption Cycle Sterilization Process	Sterility Assurance Level (SAL)	Result
Ethylene Oxide Gas	10^{-6}	Pass
LAL - AAMI ST 72:2010		Pass

12. Conclusion

The IntraNovo Microcatheter 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.