October 16, 2017

Galt Medical Corp.
David Derrick
Director of Quality and Regulatory Affairs
2220 Merritt Dr.
Garland, Texas 75041

Re: K172487
Trade/Device Name: Coaxial Dilator Set (Micro-Introducer)
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: August 15, 2017
Received: August 17, 2017

Dear David Derrick:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 (DICE) 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 (DICE) 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,

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
COAXIAL DILATOR SET (Micro-Introducer)

Indications for Use *(Describe)*
These Coaxial Dilator Sets are intended to introduce up to a 0.038 in. guidewire or catheter into the vascular system following a small gauge needle stick

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.

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K172487- 510(k) Summary

Application Date:	August 15, 2017
Application Type:	Traditional 510(k)
Applicant Information	Galt Medical Corporation 2220 Merritt Dr. Garland, TX 75041 Phone: 214-778-1306 Fax: 972-271-4706
Official Contact:	David Derrick Director of Quality and Regulatory Affairs Galt Medical Corporation 2220 Merritt Dr. Garland, TX 75041 Phone: 214-778-1306 Fax: 972-271-4706 dderrick@galtmedical.com
Device Name:	Coaxial Dilator Set (Micro-Introducer)
Device Model Number:	TBD
Classification Name:	Dilator, Vessel, for percutaneous catheterization (DRE), 21 CFR 870.1310
Device Classification:	Class II (Cardiovascular)
Predicate Device:	Coaxial Dilator Set (K000737)
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041 Phone: 214-778-5177 Fax: 972-271-4706
Establishment Registration Number:	1649395

Intended Use Coaxial Dilator Set: These Coaxial Dilator Sets are intended to introduce up to a 0.038 in. guidewire or catheter into the vascular system following a small gauge needle stick.

Device Description: The Coaxial Dilator Set (Micro-Introducer) assembly consists of an inner dilator within a slightly shorter outer sheath which is connected to the inner dilator using a spin-lock type connector. The inner and outer dilators are made from radiopaque material so they are visible under fluoroscopy. The design of the subject

device, Coaxial Dilator Set (Micro-Introducer) is unchanged from the current line of Coaxial Dilators (K000737). The subject and current marketed predicate devices are identical with the exception of the addition of an optional depth marker, optional outer hub & sheath material and additional lengths.

Comparison of Technological Characteristics: The subject device Coaxial Dilator Set (Micro-Introducer) and the predicate device have identical indication statements and are of identical design. The subject and predicate device are available in identical configurations.

	Subject Device	Predicate Device
Mfr. / Product	**Coaxial Dilator Set (Micro-Introducer) with optional depth marking, optional outer Hub & sheath material and additional length**	**Coaxial Dilator Set**
510(k) Number	K172487	K000737
Device Classification	870.1310	870.1310
Product Code	DRE	DRE
Intended use	These Coaxial Dilator sets are intended to introduce up to a 0.038 in. guidewire or catheter into the vascular system following a small gauge needle stick	These Coaxial Dilator sets are intended to introduce up to a 0.038 in. guidewire or catheter into the vascular system following a small gauge needle stick
Design	Same as predicate with the addition of optional depth marker, optional outer hub & sheath material and additional length.	The Coaxial Dilator Set assembly consists of an inner dilator within a slightly shorter outer sheath which is connected to the inner dilator using a spin-lock type connector. The inner and outer dilators are made from radiopaque material so they are visible under fluoroscopy
Color	Inner Dilator: White round hub with clear spin-lock connector, blue cylindrical cannula. Outer Sheath: Red or Grey round hub, White cylindrical cannula	Inner Dilator: White round hub with clear spin-lock connector, blue cylindrical cannula. Outer Sheath: Red or Grey round hub, White cylindrical cannula
Sizes	4F - 5F 5cm to 45cm lengths	4F - 5F 5cm to 10cm lengths
Dilator Lock	Dilator is retained	Dilator is retained

Substantial Equivalence and Summary of Bench Testing: The technological differences between the subject device and predicate device have been evaluated through bench and biocompatibility tests to provide evidence of substantial equivalence. The Coaxial Dilator Set (Micro-Introducer) with optional depth marking, optional outer Hub & sheath material and additional lengths is substantially equivalent to the specified predicate device based on comparisons of the devices functionality, compatibility, technological characteristics, and indications for use.
Design testing was conducted according to protocols based on international standards and Galt Medical requirements. Functional Testing included the following:

- Product Insertion Force
- Marking Durability
- Hub Dimensional
- Tip Dimensional
- Hub to Cannula Tensile Force
- Particulate Matter Generation

Biocompatibility testing was performed on the subject device in accordance with ISO 10993-1. Biocompatibility testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility (Hemolysis)
- Complement Activation
- In-Vitro Hemocompatibility
- Pyrogen (Materials Mediated)
- EO Residuals

Additionally the subject device was adopted into the existing ethylene oxide sterilization cycle for the Galt Coaxial Dilator cleared under K000737.

Packaging of the subject device will remain unchanged from the predicated device. Current packaging shelf life testing was provided in the predicate submission.

Conclusion: It will be shown in this 510(k) submission that the differences between the Galt Coaxial Dilator Set (Micro-Introducer) with optional depth marking, optional outer sheath material and additional lengths and the predicate devices do not raise any new questions regarding safety and effectiveness. The Galt Coaxial Dilator Set (Micro-Introducer) with optional depth marking, optional outer sheath material and additional lengths as designed and manufactured is determined to be substantially equivalent to the current marketed predicate device.

End of Section