May 30, 2019
Galt Medical Corp.
David Derrick
Director of Quality and Regulatory Affairs
2220 Merritt Drive
Garland, Texas 75087

Re: K182660
Trade/Device Name: GaltTWS
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: Class II
Product Code: DRB
Dated: April 29, 2019
Received: April 30, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Matthew Hillebrenner
Acting Division Director
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182660

Device Name
GaltTWS Stylet

Indications for Use *(Describe)*
The GaltTWS Stylet is a percutaneous catheter stylet placed inside a catheter, lead, or cannula to stiffen the device for placement or extraction.

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."

Application Date:	November 13, 2018
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:	GaltTWS Stylet
Device Model Number:	TBD
Classification Name:	Catheter Stylet (DRB), 21 CFR 870.1380
Device Classification:	Class II (Cardiovascular)
Predicate Device:	TFX Medical Coated Stylet (K992664) Guidewire (K982559) Gateway Hemostasis Valve (152528)
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041 Phone: 214-778-5177 Fax: 972-271-4706

Establishment Registration Number: 1649395

Intended Use: The GaltTWS Stylet is a percutaneous catheter stylet placed inside a catheter, lead, or cannula to stiffen the device for placement or extraction.

Device Description: The GaltTWS stylet is comprised of a stainless steel twisted/braided wire of varying diameters (0.012-0.015 inch), and varying length (30-72cm). The GaltTWS stylet can be configured as a Twisted/Braided wire bonded to a hub, flushable

hub, or connected to a flushable adjustable hub using the Galt Gateway Hemostasis Valve (K152528).

Comparison of Technological Characteristics: The subject device GaltTWS Stylet and the predicate device TFX Medical Coated Catheter Stylet have same indication and are of similar design. The subject and predicate device are available in similar configurations.

	Subject Device	Predicate Device	Predicate Device	Predicate Device
Mfr. / Product	**Galt Medical / GaltTWS Stylet**	**TFX Medical / TFX Medical Coated Catheter Stylet**	**Galt Medical / Guidewire**	**Galt Medical / Gateway Hemostasis Valve**
510(k) Number	N/A	K992664	K982559	K152528
Device Classification	870.1380	870.1380	870.1340	870.4290
Product Code	DRB	DRB	DQX	DTL
Intended use	The Galt Medical Corp. GaltTWS Stylet is a percutaneous catheter stylet placed inside a catheter, lead, or cannula to stiffen the device for placement or extraction.	The TFX Medical stylet is intended for use in conjunction with catheters or other devices, which require the aid of a stylet to render it stiff for placement.	The guidewire is intended for use in percutaneous procedures to introduce and position catheter and other interventional devices within the coronary and peripheral vasculature.	The attachable Cath Lab Hemostasis Valve is indicated to minimize blood loss during introduction of catheters, guidewires and other intravascular devices into the vasculature.
Design	A stainless steel twisted/braided wire bonded to a hub, flushable hub in a range of sizes and lengths.	A twisted/braided wire bonded to a hub in a range of sizes and lengths.	Guidewire with a tightly wound coil over a tapered core and a ribbon. The ribbon is welded to the coil at both ends. The core is welded to the coil at the proximal end.	Introducer with valved hub and luer lock connector
Sizes	Diameter - (0.012-0.015 inch) Length (30-72cm)	N/A	Diameter - (0.014-0.065 inch) Length (15-400cm)	Maximum 8FR

Substantial Equivalence and Summary of Bench Testing: The technological differences between the subject devices and predicate devices have been evaluated through bench and biocompatibility tests to provide evidence of substantial equivalence. The GaltTWS Stylet is substantially equivalent to the predicate devices based on comparisons of the devices functionality, compatibility, technological characteristics, and indications for use.

Testing was conducted according to protocols based on international standards and Galt Medical requirements. Functional Testing included the following:

- Particulate Test
- Mechanical Properties Test
- Leak Test
- Tortuous Path Test (In Vitro)

Additionally, accelerated aging was performed on the subject devices to an equivalent age of 4 years, and the physical and functional testing was repeated.

Biocompatibility testing was performed on the subject device in accordance with ISO 10993-1. This was done in order to update the biocompatibility testing to current standards, and was not done as a result of any changes to the product. Biocompatibility testing included the following:

- Cytotoxicity (MEM Elution)
- Sensitization (Magnusson – Kligman)
- Irritation (Intracutaneous injection)
- Systemic Toxicity (Systemic injection)
- Hemolysis (In Direct Contact)
- Systemic Toxicity (Materials Mediated Pyrogen)
- EO Residuals (EO, ECH, & EG)

Additionally the subject device was adopted into the existing ethylene oxide sterilization cycle for the Galt product cleared under K982559 & K152528.

Packaging of the subject device will remain unchanged from the Galt Medical Guidewire and Gateway Hemostasis Valve. Current packaging shelf life testing was provided in the predicate submissions.

Conclusion: The GaltTWS Stylet as designed and manufactured is determined to be substantially equivalent to the current marketed predicate devices.

End of Section