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

July 5, 2016

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

Re: K153533
Trade/Device Name: Tearaway Introducer Sheath and MicroSlide Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 31, 2016
Received: June 1, 2016

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. 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" (21CFR 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,

Brian D. Pullin -S

for Bram D. Zuckerman, MD
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)*
K153533

Device Name
Tearaway Introducer Sheath
MicroSlide Tearaway Introducer

Indications for Use *(Describe)*
Tearaway introducer sheath: These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature.

MicroSlide™ Tearaway introducer: These introducers are used for the procedures to introduce catheters and other intravascular devices into the coronary and peripheral vasculature of adult and pediatric patients of all ages

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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Application Date:	December 04, 2015
Application Type:	Bundled 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:	Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer
Device Model Number:	TBD
Classification Name:	Catheter Introducer (DYB), 21 CFR 870.1340
Device Classification:	Class II (Cardiovascular)
Predicate Device:	Tearaway Introducer Sheath (K000313) MicroSlide™ Tearaway Introducer (K123430)
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041 Phone: 214-778-5177 Fax: 972-271-4706
Establishment Registration Number:	1649395

Intended Use Tearaway Introducer Sheath: These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature.

Intended Use MicroSlide™ Tearaway Introducer: These introducers are used for the procedures to introduce catheters and other intravascular devices into the coronary and peripheral vasculature of adult and pediatric patients of all ages.

Device Description: The Galt Medical Tearaway Introducer Sheath assembly consists of an outer peelable sheath and a dilator. The tear-away sheath has a winged hub to initiate the tear in the sheath. The design of the tearaway introducer sheath is unchanged from the current line of Tearaway Introducer Sheaths (K000313), and the pediatric version MicroSlide™ Tearaway Introducer (K123430). The subject and current marketed predicate devices are identical with the exception of the material used in the sheath hub.

The Galt Tearaway Introducer Sheath (K000313) and Galt MicroSlide™ Tearaway Introducer (K123430) have been previously determined to be substantially equivalent. In this bundled submission, Galt Medical Corp will establish that the subject devices Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer with the replacement hub material is substantially equivalent to the current marketed devices.

Comparison of Technological Characteristics: The Tearaway Introducer Sheath with the replacement hub material is substantially equivalent to the current marketed predicate in construction, material, and device performance.

	Subject devices	**Predicate Device**	**Predicate Device**
Mfr. / Product	**Galt Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer with the new hub material**	**Galt Tearaway Introducer Sheath (K000313)**	**Galt MiroSlide™ Tearaway Introducer (K123430)**
510(k) Number	K153533	K000313	K123430
Device Classification	870.1340	870.1340	870.1340
Product Code	DYB	DYB	DYB
Intended use	**Adult Only - Tearaway Introducer Sheath**: The introducer is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature **Adult & Pediatric - MicroSlide™ Tearaway Introducer:** The introducer is used for the procedures to introduce catheters and other intravascular devices into the coronary and peripheral vasculature of	The introducer is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads into the vasculature.	The introducer is used for the procedures to introduce catheters and other intravascular devices into the coronary and peripheral vasculature of adult and pediatric patients of all ages.

	Subject devices	Predicate Device	Predicate Device
	adult and pediatric patients of all ages.		
Design	The Galt Tearaway Introducer Sheath assembly with new hub material consists of an outer peelable sheath and a dilator. The tear-away sheath has a winged hub to initiate the tear in the sheath.	The Galt Tearaway Introducer Sheath assembly consists of an outer peelable sheath and a dilator. The tear-away sheath has a winged hub to initiate the tear in the sheath.	The Galt MiroSlide™ Tearaway Introducer assembly consists of an outer peelable sheath and a dilator. The tear-away sheath has a winged hub to initiate the tear in the sheath.
Color	Sheath: Color coded winged hub, gray cannula. Dilator: White hub, green cannula	Sheath: Color coded winged hub, gray cannula. Dilator: White hub, green cannula	Sheath: Color coded winged hub, gray cannula. Dilator: White hub, green cannula
Shape	Sheath: winged hub, cylindrical cannula Dilator: Round hub, cylindrical cannula	Sheath: winged hub, cylindrical cannula Dilator: Round hub, cylindrical cannula	Sheath: winged hub, cylindrical cannula Dilator: Round hub, cylindrical cannula
Sizes	Adult Only - **Galt Tearaway Introducer Sheath** 3F - 16F 5 cm and 30 cm & Adult/Pediatric - **Galt MicroSlide™ Tearaway Introducer** 2F - 3F 3 cm and 7 cm	Adult - **Galt Tearaway Introducer Sheath** 3F – 16F 5cm to 30cm lengths	Adult/Pediatric - **Galt MicroSlide™ Tearaway Introducer** 2F – 3F 3cm to 7cm lengths
Dilator Lock	Dilator is retained	Dilator is retained	Dilator is retained

Use Type: The Galt Tearaway Introducer Sheath and MiroSlide™ Tearaway Introducer is a single patient use, disposable device.

Summary of Non-Clinical Data Submitted: Functional testing on aged product was conducted to verify that the Tearaway Introducer Sheath and MiroSlide™ Tearaway Introducer with replacement hub material met product specifications and is substantial equivalent to the current marketed predicate devices. Testing was conducted according to protocols based on international standards and Galt Medical requirements.
Functional Testing included the following:

- Hub Break Force
- Perpendicular Pull Force
- Dilator Insertion Test
- Hub Dimensional

Additionally the Tearaway Introducer Sheath and MiroSlide™ Tearaway Introducer with replacement hub material was adopted into the existing ethylene oxide sterilization cycle for the Galt Tearaway Introducer Sheath cleared under K000313 and Galt MiroSlide™ Tearaway Introducer cleared under K123430.

Biocompatibility testing was performed on the Tearaway Introducer Sheath with replacement hub material. Biocompatibility Testing included the following:

- Cytotoxicity
- Sensitivity
- Irritation
- Systemic Toxicity
- Hemocompatibility (Hemolysis)
- Pyrogen (Materials Mediated)
- EO Residuals

Packaging will remain unchanged from the predicated devices. Current packaging shelf life testing was provided in the predicate submissions.

Conclusion: It will be shown in this 510(k) submission that the differences between the Galt Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer with replacement hub material and the predicate devices do not raise any questions regarding safety and effectiveness. The Galt Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer with replacement hub material as designed and manufactured is determined to be substantially equivalent to the current marketed predicate devices.

End of Section