Section 5 - 510(k) SUMMARY

APR 1 2 2013

Manufacturer:	Galt Medical
	2220 Merritt Drive
	Garland, TX 75041
Official Contact:	David Derrick, Director of Quality and Regulatory Affairs
Date Prepared:	November 02, 2012

Device Information:

Device Name:	MicroSlide™ TearAway Introducer
Device Model Number:	TBD
Classification Name:	Catheter Introducer (DYB),
	21 CFR 870.1340
Device Classification:	Class II (Cardiovascular)

Predicate Devices:

Device 1	Tearaway Introducer Sheath, Galt Medical - K000313 (Xentek Medical)
	Device Class: II
Device 2	Galt VTI™ Valved Tear-away Introducer, Galt Medical - K112398
	Device Class: II
Device 3	Super Sheath Introducer Sheath, Togo Medikit Co. Ltd., K121504
	Device Class: II

Intended Use: The MicroSlide™ Tearaway Introducer System is intended for use in percutaneous 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 MicroSlide™ Tearaway Introducer is constructed using identical processes and materials as the predicate devices; Tearaway Introducer Sheath, Galt Medical, K000313 with the addition of smaller sizes 2 & 3French, and the Galt VTI™ Valved Tear-away Introducer, K112398 without the hemostasis valve.

The MicroSlide™ Tearaway Introducer device consists of two components; a dilator and an outer sheath. The outer sheath is a one piece, molded hub/sheath "tearaway" design that with minimal force will break and separate at the hub/wing to facilitate the removal of the sheath tube from the patient by peeling/splitting the tub longitudinally down its length. The dilator tube is an open plastic tube with an integral molded luer hub for guidewire insertion. The dilator is longer than the outer sheath with a tapered distal tip. The sheath hub and dilator hub lock together using a rotating motion to add in insertion of the device into the vasculature.

Materials of Construction:

Dilator hub: The hub of the dilator is made from a polyamide co-polymer resin base material with a white colorant .

Dilator Tube: The dilator tube is made from a polyamide co-polymer resin base material with a green colorant.

Sheath hub (wing): The sheath hub is made from a high density polypropylene base material with a blue or purple colorant depending on the French size.

Sheath tube: The sheath tube is made from PTFE, w/bismuth trioxide loading and a gray colorant.

Comparison of Technological Characteristics and Substantial Equivalence:

The following table summarizes the technological comparison of the MicroSlide™ Tearaway Introducer and the predicate devices, Galt Tearaway Introducer, VTI™ Valved Tear-away Introducer, and Togo Medikit Super Sheath Introducer Sheath.

		Subject device	Predicate 1	Predicate 2	Predicate 3
Mfr. / Product		**Galt MicroSlide™ Tearaway Introducer**	**Galt Tearaway Introducer**	**Galt VTI™ Valved Tearaway Introducer**	**Togo Medikit Super Sheath Introducer Sheath (3.3F)**
510(k) Number		**K123430**	K000313	K112398	K121504
Device Classification		870.1340	870.1340	870.1340	870.1340
Product Code		DYB	DYB	DYB	DYB
Intended use		These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads into the coronary and peripheral vasculature of adult and pediatric patients of all ages.	These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads into the vasculature.	These introducers are used for the percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.	These introducers are used in the introduction of diagnostic and interventional device inserted into human vasculature of adult and pediatric patients of all ages
Performance Specifications	**Insertion Force(Avg.)**	**2Fr** = 82.4 grams **3Fr**= 95.5 grams	N/A	N/A	N/A
	Hub Break Force	2.0 lbs - 5.5 lbs	2.0 lbs - 5.5 lbs	2.0 lbs - 10.0 lbs	N/A
	Sheath Peel Strength	**2Fr** = 0.20 – 1.00 lbs **3Fr**= 0.20 – 1.70 lbs	**4 - 15Fr** = 0.20 – 1.70 lbs **16Fr**= 0.20 – 2.25 lbs	**4 - 15Fr** = 0.20 – 1.70 lbs **16Fr**= 0.20 – 2.25 lbs	N/A
	Sheath/Hub strength	**2Fr** = 2.0 lbs min. **3Fr** = 3.0 lbs min.	3.0 lbs min.	**6 - 15Fr** = 2.6 lbs min. **16Fr** = 3.3 lbs min.	N/A
Design		Tear-away introducer with winged sheath hub and locking dilator		Tear-away introducer with winged sheath hub, integrated hemostasis valve, optional side port, w/stopcock and locking dilator	Introducer with round sheath hub, integrated hemostasis valve, side port, w/stopcock and locking dilator
Color		Gray sheath with color coded hub, Green dilator cannula			White Sheath with color coded hub, green dilator cannula
Shape		Cylindrical cannula with winged hub			Cylindrical cannula with round hub
Sizes		3cm, and 7cm, lengths sizes 2F – 3F	14cm, 30cm, 44cm and 50cm lengths sizes 4F – 16F	13cm, and 23cm, lengths sizes 6F – 16F	5cm, and 7cm, lengths 3.3 F size
Shelf life		4 years			3 Years
Sterilization		Ethylene Oxide (SAL 10^{-6})			Ethylene Oxide
Packaging Configurations		• Finished single sterile device • Finished sterile kit			• Finished single sterile device • Finished sterile kit

Use Type: The MicroSlide ™ Tearaway Introducer is a single patient use, disposable device.

Summary of Non-Clinical Data Submitted: Functional testing was conducted to verify that the 2F & 3F MicroSlide™ Tearaway Introducer met product specifications. Testing was conducted according to protocols based on international standards and Galt Medical requirements. Functional Testing included the following:

- Penetration (Insertion) Force Test – Ref. XE-022
- Sheath Peel Force Test – Ref. XE-022
- Sheath Perpendicular Pull Test– Ref. XE-022
- Dilator Pull Test– Ref. XE-022

Additionally the finished single device and kit versions of the 2F & 3F MicroSlide™ Tearaway Introducers were adopted into the existing ethylene oxide sterilization cycle for the Tearaway Introducer and Galt VTI products which was validated in accordance with ISO 11135-1 using a frictional cycle/overkill approach to a sterility assurance level (SAL) of 10^{-6}. The ethylene oxide sterilization validation report is provided in Section 14, **TAB 14.1**

Biocompatibility testing was performed on the predicate devices provided in K000313 and K112398. The devices tested under K000313 and K112398 included raw materials and packaging materials utilized in the 2F & 3F MicroSlide™ Tearaway Introducers and is included in Section 15, **TAB 15.1** of this 510(k) premarket notification. Additional testing was not conducted.

Packaging and product shelf life testing was conducted according domestic and international standards and in-house requirements, and includes the following:

- Package integrity (Visual)
- Package integrity (Bubble Emission)
- Sheath Peel Force Test
- Sheath Perpendicular Pull Test
- Dilator Pull Test

Final reports for packaging and product shelf life testing is provided in Section 18, **TAB 18.2** , Test 0546 and **TAB 18.3,** Test 0541 of this 510(k) premarket notification.

Summary of Risk Management: Risk assessment is addressed in the Risk Management Report and FMEA "Tearaway Products Family", FMEA-022. Current controls have been identified and all potential Failure Modes identified in the FMEA currently fall into the "Broadly Acceptable" region as defined by Galt procedure # OP-072, Conducting Failure Mode and Effects Analysis. The risk analysis for the MicroSlide™ and Tearaway Introducer family is provided in Section 12, **Tab 12.1.**

Conclusion of Substantial Equivalence: The basis of substantial equivalence for the MicroSlide™ 2F & 3F Tearaway Introducer is based on the similarities in intended use, materials, function, performance, sterilization, design, technology and operational principle to the predicate devices. Risks associated with the smaller French sizes and new patient population were assessed and mitigated if applicable.

Due to these similarities, Galt Medical believes that the MicroSlide™ 2F & 3F Tearaway Introducer does not raise any new safety or effectiveness issues and is determined to be substantially equivalent to the referenced predicate devices.

End of Section

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 12, 2013

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

Re: K123430
Trade/Device Name: MicroSlide Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 21, 2013
Received: March 22, 2013

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) number (if known): K123430

Device Name: MicroSlide™ Tearaway Introducer

Indications for Use:

The Introducer System is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the coronary and peripheral vasculature of adult and pediatric patients of all ages

Prescription Use__X__ (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use_____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner