September 26, 2019

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

Re: K192195
Trade/Device Name: Sterile Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: September 18, 2019
Received: September 19, 2019

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. 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,

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: 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)*
K192195

Device Name
STERILE DILATOR

Indications for Use *(Describe)*
These dilators are used for the percutaneous introduction of guidewires into the peripheral vasculature.

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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510(k) Summary

Application Date:	August 12, 2019
Application Type:	Special 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:	Sterile Dilator
Device Model Number:	TBD
Classification Name:	Dilator, Vessel, for percutaneous catheterization (DRE), 21 CFR 870.1310
Device Classification:	Class II (Cardiovascular)
Predicate Device:	Primary predicate device: Coaxial Dilator Set (Micro-Introducer) K172487. Reference Devices: Galt Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer with new material hub K153533 and Elite HV Radial (CathLab Introducer) K173287
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041
Establishment Registration Number:	1649395

Intended Use: These dilators are used for the percutaneous introduction of guidewires into the peripheral vasculature.

Device Description: The dilator introducer consists of a tipped radiopaque tube with a molded hub that accepts up to a .038-inch guidewire

Comparison of Technological Characteristics: The Dilator is substantially equivalent to the unmodified predicate in construction, materials, and device performance. As per indication of use, the subject device just as the predicate will also accept up to 0.38inch guidewire. And although it doesn't mention the introduction of catheters like the predicate device does, this difference in indication of use does not in any way affect substantial equivalence of the device to the primary predicate.

	Subject device	Primary Predicate device	Reference Predicate Device	Reference Predicate Device
Mfr. / Product	**Sterile Dilator**	**Coaxial Dilator Set (Micro-Introducer)**	**Galt Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer with new material hub**	**Elite HV Radial (CathLab Introducer)**
510(k) Number		K172487	K153533	K173287
Device Classification	870.1310	870.1310	870.1340	870.1340
Product Code	DRE	DRE	DYB	DYB
Intended use	These dilators are used for the percutaneous introduction of guidewires into the peripheral vasculature	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	**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	Elite HV Radial is indicated to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery

	Subject device	Primary Predicate device	Reference Predicate Device	Reference Predicate Device
			pediatric patients of all ages.	
Design	The dilator is composed of hub over-molded onto a tube. The material for 5.5F and smaller dilators is Pebax 7233 SA01. And 6F and above dilators are made with HDPE. The dilator introducer consists of a tipped radiopaque tube with a molded hub that accepts up to a .038 inch guidewire	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 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.	Introducer with valved sheath and dilator in a range of sizes and lengths

	Subject device	Primary Predicate device	Reference Predicate Device	Reference Predicate Device
Color	Dilator: White or Grey hub, green cannula	Inner Dilator: White round hub with clear spin-lock, blue cylindrical cannula Outer Sheath: Red or Grey round hub, white cylindrical cannula	Sheath: Color coded winged hub, gray cannula. Dilator: White hub, green cannula	Sheath Hub – White Sheath cannula- White Sheath cap- Various indicating Fr size Dilator hub- White Dilator cannula- Blue Sidearm with stopcock – Clear Valve silicone - clear natural Valve TPE - clear natural
Shape	Cylindrical cannula with round hub	Inner Dilator: round hub with spin-lock, cylindrical cannula Outer Sheath: round hub, cylindrical cannula	Sheath: winged hub, cylindrical cannula Dilator: Round hub, cylindrical cannula	
Sizes	3F-16F 10cm to 30 cm lengths	4F- SF 5cm to 45cm lengths	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	4F - 6F 5cm to 25cm lengths
Packaging	Pouch- Uncoated 10738 Tyvek, 92 GA PET/ 3 mil LDPE (4 mil total)	Pouch- Uncoated 10738 Tyvek, 92 GA PET/ 3 mil LDPE (4 mil total)	Pouch- Uncoated 10738 Tyvek, 92 GA PET/ 3 mil LDPE (4 mil total)	Pouch- Uncoated 10738 Tyvek, 92 GA PET/ 3 mil LDPE (4 mil total)

Use Type: The Galt Sterile Dilator is a single patient use, disposable device.

Summary of Non-Clinical Data Submitted: Performance testing done to evaluate the Galt sterile dilators included Design Verification and packaging validation testing on un-aged and 4 year aged product. This demonstrates that the Galt sterile dilators as stand-alone products meet the pre-defined product specification to those found in the primary predicates introducer assembly device Coaxial Dilator set cleared under 510(k) K172487,

as well as predicate reference devices Galt Tearaway Introducer Sheath & MicroSlide™ Tearaway Introducer K153533 and Elite HV Radial (CathLab Introducer) K173287.

Testing was conducted according to protocols based on international standards and Galt Medical requirements. The following physical and mechanical test were done and all test passed successfully:

Attributed Tested	**Specification**	**Results**
Dimensional	Comparison between predicate device and subject device. Including; **<u>Dimensional Comparison:</u>** Predicate Spec range: **Min size dilator 3F** • ID at Tip; 0.012' -0.020' • Effective length; 12.05' - 12.45' • Through hole ID; 0.021' - 0.025' **Most common long length: 9F** • ID at Tip; 0.038' -0.040' • Effective length; 33.48' - 34.12' • Through hole ID; N/A **Max size dilator 16F** • ID at Tip: 0.038' -0.040' • Effective length; 17 .55' - 17.85' • Through hole ID; N/A	Passed: All sampled dilator sizes within spec range
Descriptive	Comparison to predicate including; • labeling (labels, IFU, promotional materials) • Intended use and instructions including anatomical placement for the distal tip • Materials used to fabricate the devices	Passed: All labeling, IFU and promotional materials were identical to predicate.
Mechanical specifications	• Predicate Spec range • Tensile strength of dilator body-min 5lbs • Tensile strength of dilator body to hub- min 5lbs	Passed: All sampled dilator sizes passed test within acceptance range
Particulate Test	Confirm acceptable levels of particulate	Passed: Test article exhibited particulate levels equal to or less than predicate equal
Simulated use Test	Measure Insertion force; Force must be ≤ 20% of predicate	Passed: All sampled dilators with range

Packaging Test	Packaged should not be damaged after all test. Seal must remain intact. • Shipping test • Pouch Test worst case scenario • Atmospheric conditioning • ISTA 2A-2011 Partial simulation performance test procedure for packaged products 150lb (68kg) or less.	Passed: No package was damaged. Visual inspection passed. No pouches were damaged.

Conclusion: It will be shown in this 510(k) submission that Galt sterile dilators as stand-alone products are favorably compared with those found in the assembly sets of the predicates introducer devices. All Galt dilators have been manufactured and marketed for many years as a component of various introducers assemblies, and their use in the market as a stand-alone sterile dilator is substantially equivalent to listed predicates.

End of Section