December 21, 2017

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

Re: K173287
Trade/Device Name: Elite HV Radial
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 13, 2017
Received: October 16, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Kenneth J. Cavanaugh -S

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)*

K173287

Device Name
ELITE HV RADIAL

Indications for Use *(Describe)*

The Galt Medical Corp 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.

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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Section 5 – 510(k) Summary

Application Date:	October 13, 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:	Elite HV Radial
Device Model Number:	TBD
Classification Name:	Catheter Introducer (DYB), 21 CFR 870.1340
Device Classification:	Class II (Cardiovascular)
Predicate Device:	Glidesheath (K152173) Elite HV (K043525 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 Galt Medical Corp 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.

Device Description: The Galt Medical Corp Elite HV product has been on the market since February of 2005, and was cleared under 510(k) K043525. The clearance included sizes from 4-9FR, and lengths from 5-110 cm with the following indication for use:

The Sheath Introducer system is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the vasculature.

The purpose of this 510(k) is to expand that indication for use for the Elite HV products to include radial placement. There were no design changes required as the current Galt offering included sizes which are appropriate for radial placement. The only limitation of the Radial placement claim is that the range of sizes is more limited due to the target anatomy.

The Elite HV and Elite HV Radial consists of an introducer (valved sheath with sidearm and stopcock and dilator), which are packaged together with a guide wire. The Elite HV product is configured with a silicone valve or a TPE valve cleared under 510(k) K152528. Some product configurations also include an entry needle, guide wire inserter and a flushing syringe. The Elite HV Radial is used to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery. The sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel. In addition, the sheath and dilator contain barium sulfate, making these devices visible under fluoroscopy.

Comparison of Technological Characteristics: The subject device Elite HV Radial and the predicate device Terumo Glidesheath have identical indication statements 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 / Elite HV Radial**	**Galt Medical / Elite HV**	**Terumo / Glidesheath™**	**Galt Medical / Gateway Hemostasis Valve**
510(k) Number		K043525	K152173	K152528
Device Classification	870.1340	870.1340	870.1340	870.4290
Product Code	DYB	DYB	DYB	DTL
Intended use	The Galt Medical Corp 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.	The Galt Medical Corp Elite HV is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the vasculature.	The Glidesheath™ is indicated to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.	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	Introducer with valved sheath and dilator in a range of sizes and lengths	Introducer with valved sheath and dilator in a range of sizes and lengths	Introducer with valved sheath and dilator in a range of sizes and lengths	Introducer with valved hub and luer lock connector
Color	Sheath Hub – White	Sheath Hub – White	Sheath Hub – Various	Sheath Hub – White

	Subject Device	**Predicate Device**	**Predicate Device**	**Predicate Device**
	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	Sheath cannula- White Sheath cap- Various indicating Fr size Dilator hub- White Dilator cannula- Blue Sidearm with stopcock – Clear Valve silicone - clear natural	Sheath cannula- White Sheath cap- Various indicating Fr size Dilator hub- Various indicating Fr size Dilator cannula- Blue Sidearm with stopcock – Clear Valve - clear	Sheath cap- Various indicating Fr size Sidearm with stopcock – Clear Valve TPE - clear natural
Sizes	4F - 6F 5cm to 25cm lengths	4F - 9F 5cm to 110cm lengths	4F - 6F 10cm to 25cm lengths	Maximum 8FR
Dilator Lock	Dilator is retained in sheath cap	Dilator is retained in sheath cap	Dilator is retained on sheath cap	Not applicable

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 Elite HV Radial is substantially equivalent to the specified predicate device 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
- Lubricity Test
- Durability of coating
- Dimensional comparison test

Additionally, accelerated aging was performed on the subject devices to an equivalent age of 4 years, and the 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 (Direct Contact)
- Hemocompatibility (Complement Activation)
- In-Vitro Hemocompatibility (Dog Thrombogenicity)
- 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 K043525 & K152528.

Packaging of the subject device will remain unchanged from the Galt Elite HV products. 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 Elite HV Radial and the predicate devices do not raise any new questions regarding safety and effectiveness. The Galt Elite HV Radial as designed and manufactured is determined to be substantially equivalent to the current marketed predicate device.

End of Section