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

December 02, 2015

Galt Medical Corp.
David Derrick
Director Of Quality And Regulatory Affairs
2220 Merritt Dr.
Garland, Texas 75041

Re: K152528
Trade/Device Name: Attachable Cath Lab Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, Or Fitting
Regulatory Class: Class II
Product Code: DTL
Dated: September 1, 2015
Received: September 3, 2015

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" (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.

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 yours,

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): K152528

Device Name: Attachable Cath Lab Hemostasis Valve

Indications for Use:

The Attachable Cath Lab Hemostasis Valve is indicated to minimize blood loss during the introduction of catheters, guidewires and other intravascular devices into the vasculature.

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)

Section 5 – 510(k) Summary

Application Date:	September 01, 2015
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:	Attachable Cath Lab Hemostasis Valve
Device Model Number:	TBD
Classification Name:	Cardiopulmonary bypass adaptor, Stopcock, Manifold, or Fitting (DTL), 21 CFR 870.4290
Device Classification:	Class II (Cardiovascular)
Predicate Device:	Merit Medical IN-LINE Hemostasis Valve (K990975) Galt Medical Cath Lab Introducer Sheath (K043525) Galt VTI® Valved Tearaway Introducer Sheath (K112398)
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041 Phone: 214-778-5177 Fax: 972-271-4706
Establishment Registration Number:	1649395

Intended Use: The Attachable Cath Lab Hemostasis Valve is indicated to minimize blood loss during the introduction of catheters, guidewires and other intravascular devices into the vasculature.

Device Description: The Galt Medical Attachable Cath Lab Hemostasis Valve assembly consists of a molded hub with an integrated hemostasis valve, sideport tubing with 3 way stopcock. The design of the Attachable Cath Lab Hemostasis Valve is derived directly from the current line of Galt Medical Cath Lab Introducer Sheath (K043525). The subject and predicate device are both have an integrated hemostasis valve, and side port tubing with stopcock.

The Galt Cath Lab Introducer (K043525) has been previously determined to be substantially equivalent. In this submission, Galt Medical Corp will establish that the subject device Attachable Cath Lab Hemostasis is substantially equivalent to the current marketed devices; Merit Medical IN-LINE Hemostasis Valve, Galt Cath Lab Introducer Sheath and Galt VTI Valved Tearaway Introducer.

Comparison of Technological Characteristics: The Attachable Cath Lab Hemostasis Valve is substantially equivalent to the unmodified predicate in construction, materials, and device performance.

	Subject device	**Predicate Device**	**Predicate Device**	**Predicate Device**
Mfr. / Product	**Galt Medical Attachable Cath Lab Hemostasis Valve**	**Merit Medical IN-LINE Hemostasis (K990975)**	**Galt Medical Cath Lab Introducer (K043525)**	**Galt Medical VTI Valved Tearaway (K140028)**
510(k) Number	N/A	K112398	K043525	K140028
Device Classification	870.4290	870.4290	870.1340	870.1340
Product Code	DTL	DTL	DYB	DYB
Intended use	Intended to minimize blood loss during the introduction of catheters, guidewires and other intravascular devices into the vasculature	Intended to minimize blood loss during the introduction of catheters, guidewires and other intravascular devices into the vasculature	The seath introducer system is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the vasculature.	These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads into the vasculature.

	Subject device	Predicate Device	Predicate Device	Predicate Device
Design	The Galt Attachable Cath Lab Hemostasis Valve assembly consists of a molded hub with an integrated hemostasis valve, sideport tubing with 3 way stopcock.	The Merit Medical IN-LINE Hemostasis Valve assembly consists of a molded hub with an integrated hemostasis valve, sideport tubing with 3 way stopcock.	Cath Lab introducer has a molded hub/sheath with integrated hemostasis valve, and side port tubing with stopcock. The device includes a locking dilator to assist in the insertion of the device into the vascular system.	The VTI valved tearaway introducer has a molded hub/sheath with integrated hemostasis valve, and side port tubing with stopcock. The device includes a locking dilator to assist in the insertion of the device into the vascular system
Color	White or Green Colored hub and cap with clear sideport tubing and stopcock	White Colored hub with clear sideport tubing and stopcock	White Colored hub, color coded cap with clear sideport tubing and stopcock	Color coded hub, clear cap with clear sideport tubing and stopcock
Shape	Round hub with spinlock collar	Round hub with spinlock collar	Cylindrical cannula with round hub	Cylindrical cannula with winged hub
Sizes	Accepts up to 8F device	Accepts up to 8F device	6cm, to120cm lengths, sizes 4F – 9F	13cm, and 23cm lengths, sizes 6F – 16F
Pressure withstand	7 PSI	7 PSI	7 PSI	6.1 PSI
Vacuum Withstand	0.47in-Hg	0.47in-Hg	0.47in-Hg	0.47in-Hg
Dilator Lock	N/A	N/A	Dilator is retained	Dilator is retained

Use Type: The Galt Attachable Cath Lab Hemostasis Valve is a single patient use, disposable device.

Summary of Non-Clinical Data Submitted: Functional testing on 4 year aged product was conducted to verify that the Attachable Cath Lab Hemostasis Valve met product specifications. Testing was conducted according to protocols based on international standards and Galt Medical requirements. Functional Testing included the following:

- Pressure Leak Test
- Vacuum Leak Test
- Guidewire Insertion Test
- Dilator Insertion Test
- Sidearm Tubing to Hub Pull Force Test
- Spinlock Collar Adapter Pull Test

Additionally the Attachable Cath Lab Hemostasis Valve was adopted into the existing ethylene oxide sterilization cycle for the Galt Cath Lab Introducer Sheath cleared under K043525.

Biocompatibility testing was provided in Galt Cath Lab Introducer Sheath submission K043525 and for the optional valve - Galt VTI Valved Tearaway Introducer submission K140028. The devices tested included identical raw materials and package configuration and materials utilized in the Galt Attachable Cath Lab Hemostasis Valve and Galt VTI Valved Tearaway Introducer.

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 Attachable Cath Lab Hemostasis Valve and the predicate device do not raise any questions regarding safety and effectiveness. The Galt Attachable Cath Lab Hemostasis Valve as designed and manufactured is determined to be substantially equivalent to the referenced predicate device.

End of Section