510(k) SUMMARY

(as required by section 807.92(c))

Device Name:	GaltVTI™ Valved Tearaway Introducer
Device Models:	The GaltVTI™ is offered with a standard or a flexible dilator and an optional side port. The products are offered sterile or bulk non-sterile.
Classification Name:	Catheter Introducer (DYB), 21 CFR 870.1340
Device Classification:	Class II (Cardiovascular)
Predicate Devices:	Tearaway Introducer Sheath, K000313 Catheter Introducer, K043525
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041
Establishment Registration Number:	1649395
Official Contact:	Betsy Cortelloni Corporate Director of Quality and Regulatory Affairs Theragenics Corporation 5203 Bristol Industrial Way Buford, GA 30518 Phone: 770-831-4294; Fax: 770-831-4369 cortellb@theragenics.com

Intended Use: The Introducer System is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.

Device Description: The finished device is a tear-away introducer for use in percutaneous procedures to introduce or position catheters or other interventional devices into the peripheral vasculature. The unmodified predicate introducers are constructed of the same or similar materials. The device is being modified to add a tear-away hemostasis valve. The combined performance characteristics of the predicate devices are unchanged and are consistent with other legally marketed predicate devices.

Comparison of Technological Characteristics: The GaltVTI™ Valved Tearaway Introducer is substantially equivalent to the unmodified predicates in materials, construction, and in device performance.

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

Performance Testing: Design verification included leak testing, force testing, hub break force, perpendicular pull and shelf-life test. The following biocompatibility tests were also performed: cytotoxicity, sensitization, irritation, systemic toxicity, hemolysis, and hemocompatibility (complement activation and in-vivo thrombogenicity.)

Conclusion: The results of the DV testing confirmed that design inputs were achieved and the cumulative test results demonstrated the functionality, safety and effectiveness of the Valved Tearaway Introducer, as well as its substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

APR 12 2012

Theragenics Corporation
c/o Ms. Betsy Cortelloni
Corporate Director of Quality and Regulatory Affairs
5203 Bristol Industrial Way
Buford, GA 30518

Re: K112398
Trade/Device Name: GaltVTI™ Valved Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 9, 2012
Received: March 13, 2012

Dear Ms. Cortelloni:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (240) 276-3150 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 FORM

510(K) number (if known): K112398

Device Name: GaltVTI™ Valved Tearaway Introducer

Indications for Use:

The Introducer System is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112398