FEB - 9 2005

510(k) Summary of Safety and Effectiveness for
Galt Medical Corp. Catheter Introducer
(Prepared in accordance with 21 CFRPart 807.92)
Date 12/14/04

K043525

(1) **Submitter**: Galt Medical Corp.
2475 Merritt Drive
Garland, TX 75041
(972) 271-5177
Contact Person: David Catlin

(2) Device Name: **Catheter Introducer**
Trade Name: No proprietary name has been established.
Classification Name: Catheter Introducer
Classification Code: DYB

(3) **Substantial Equivalency:** Galt Medical Catheter Introducer is substantially equivalent to Catheter Introducers from:

Galt K000313

(4) **Device Description:** The materials of construction are consistent with introducers presently in commercial distribution. The product is available in 4 French to 9 French. The sheath lengths are 5cm to 110cm.

(5) **Technological Characteristics:** Galt Medical's Catheter Introducer has the same indications for use and are otherwise technically the same as the predicate devices.

(6) **Non-Clinical Tests:** The results of these tests demonstrated that the functionality and performance Characteristics of the introducers are comparable to the currently marketed introducers. Test performed included: tensile strength, and valve leakage.

(7) **Conclusions:** Based on the information presented in this 510(k) premarket notification, Galt Medical's catheter introducers are considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

Mr. David G. Catlin
Executive Vice President
Galt Medical Corp.
2475 Merritt Drive
Garland, TX 75041-6146

Re: K043525
Trade/Device Name: Catheter Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: II
Product Code: DYB
Dated: January 7, 2005
Received: January 10, 2005

Dear Mr. Catlin:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochnes

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

Enclosure

K043525

Indications for Use

510(k) Number (if known): K043525

Device Name: Catheter Introducer

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

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

Donna R. Vochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043525