K982559

FEB 1 1999

510(k) Summary of Safety and Effectiveness for Galt Medical's Guidewires

(Prepared in accordance with 21 CFRPart 807.92)
Date 1/28/99

510(k) Number: K982559

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

(2) **Device Name**: Guidewire
Trade Name: No proprietary name has been established.
Classification Name: Wire, Guide, Catheter
Classification Code: 74DQX

(3) **Substantial Equivalency**: Galt Medical Corp.'s guidewires are substantially equivalent to guidewires from: Argon Medical
Cordis
Cook
Acme 510(k) K920884

(4) **Device Description and Intended Use:** The material of construction is stainless steel which is consistent with guidewires presently in commercial distribution. The wires are also manufactured using a PTFE coating. The wires are available straight, with "J" end, or moveable core. The wires range from .014" diameter through .065" diameter and lengths from 15cm. to 400cm.

These guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

(5) **Technological Characteristics:** Galt Medical's guidewires have 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 guidewires are comparable to the currently marketed guidewires. Tests performed include: tensile strength, torque strength, torqueablility, flexibility, and coating adherence.

(7) **Conclusions:** Based on the information presented in this 510(k) premarket notification, Galt Medical's guidewires 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 1 1999

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

Re: K982559
Trade Name: Guidewire
Regulatory Class: II
Product Code: DQX
Dated: January 19, 1999
Received: January 20, 1999

Dear Mr. Catlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to

your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982559

Device Name: GUIDEWIRE

Indications For Use:

These guidewires are intended for use in percutaneous procedure to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

(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, Respiratory,
and Neurological Devices
510(k) Number K982559

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)