4-7-99

K981191

IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112 USA

phone (651) 697-9797
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IntraTherapeutics

510(k) Summary

Product Name: ITI IntraMAX™ guide catheter
Common Name: percutaneous catheter

Submitter's Name:
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Official Contact:
Amy Peterson
Vice President RA and QA
Tel. 612-697-2076
Fax 612-697-2085

Summary Preparation Date: September 1, 1998

This summary is provide in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission.

The ITI IntraMAX™ guide catheter is a Class II product classified as a percutaneous catheter (21 CFR §870.1250). Substantial equivalence is claimed to the Cordis Vista Brite Tip®, Mallinckrodt Trax Craven, and SciMed Cyber guide catheters.

The ITI IntraMAX™ guide catheters are single lumen devices designed to aid the physician in the access of distal vasculature with the aid of a guidewire. The ITI IntraMAX™ guide catheters are a family of catheters currently manufactured in three French sizes (6, 7 and 8 FR), in lengths 65-110 cm and with multiple distal stem configurations ("style features"). The style features are offered with differing handling characteristics to allow flexibility in meeting physician preferences within the indication for use.

The intended use is "for intravascular introduction of diagnostic, therapeutic and interventional devices into the extracranial vasculature ".

Technological characteristics were assessed through comparison bench tests and results demonstrated, at minimum, equivalence performance characteristics between the ITI IntraMAX™ guide catheter and predicate devices. Bench tests included tensile, introducer resistance, kink resistance, torque, body stock stiffness, stem shape recovery and back-up support. All appropriate biocompatibility tests for a guide catheter were successfully completed per ISO 10993-1. The guide catheter is provided sterile.

The composite results of these tests indicate the ITI IntraMAX™ guide catheter is safe for the intended use with a shelf life of two years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 1999

Ms. Amy Peterson
Vice Presidrent RA and QA
Intra Therapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Re: K981191
Trade Name: ITI IntraMAX™ Guide Catheter
Regulatory Class: II
Product Code: DQY
Dated: January 7, 1999
Received: January 8, 1999

Dear Ms. Peterson:

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.

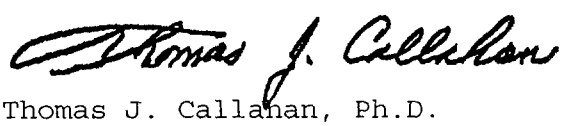
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, 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 know): _____K981191_____

Device Name: ITI IntraMAX™ 91, 78, and 65

Indication For Use:

The ITI IntraMAX™ Guide Catheter is intended for intravascular introduction of diagnostic, therapeutic and interventional devices into the extracranial vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTIUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number_____

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)