K992622

SEP 29 1999

510(k) Summary

Product Name: IntraMax™ Guide Catheter

Common Name: guide or guiding catheter

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

Official Contact: Amy Peterson
VP Regulatory Affairs & Quality Assurance
Tel. 651-697-2076 Fax 651-697-2080

Summary Preparation Date: July 27, 1999

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 product trade and common name are IntraMax™ Guide Catheter and guide/guiding catheter, respectively. This is a Class II product classified under 21 CFR §870.1250 as a percutaneous catheter. Substantial equivalence* is claimed to IntraTherapeutics, Inc. ITI IntraMax™ Guide Catheter (K981191).

The IntraMax™ is single lumen devices designed to aid the physician in the access of distal vasculature with the aid of a guidewire. The IntraMax™ is a family of catheters currently manufactured in three French sizes (6, 7 and 8 FR), multiple distal stem configurations, lengths and side holes ("style features"). Per French size, catheters will be 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".

Summary of technological characteristics: functional testing was performed to ensure the IntraMax™ would function according to its intended use instructions. Biocompatibility tests per ISO 10993 were also performed and were in compliance with ISO and GLP requirements. All testing conducted confirmed the acceptability of the IntraMax™ for the intended purpose.

The IntraMax™ remains substantially equivalent* to the predicate guide catheter for intravascular introduction of diagnostic, therapeutic and interventional devices into the extracranial vasculature.

As demonstrated the IntraMax™ is identical for indication for use and equivalent in materials and technological characteristics. Performance functional testing (bench) further supports a substantial equivalence claim. The collective evidence therefore provides assurance that the IntraMax™ Guide Catheter meets the requirements that are considered acceptable for the intended use.

**This document uses the term "substantial equivalence" as intended in 21 CFR 807.87, and not as defined in Title 36 of the US Code.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1999

Ms. Amy Peterson
Vice President Regulatory Affairs & Quality Assurance
Intra Therapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Re: K992622
Trade Name: IntraMax™ Guide Catheter
Regulatory Class: II
Product Code: DQY
Dated: September 9, 1999
Received: September 10, 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

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): K992622

Device Name: IntraMax™ Guide Catheter

Indication For Use: The 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 - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992622

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