JUL 21 1998

K980290

p 1 of 2

510(k) Summary (Page 1 of 2)

Product Name: ITI Stent
Common Name: Biliary 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: January 23, 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 product trade and common name are ITI Stent and biliary catheter, respectively. This is a Class II product classified under 21 CFR §8768.5010 as a biliary catheter and accessories. Substantial equivalence is claimed to Cordis Corporation, legally marketed PALMAZ™ and PALMAZ-SCHATZ™ Balloon-Expandable Biliary Stent (K905720, K911581, K964688).

IntraTherapeutics, Inc. device is a balloon expandable stainless steel stent with an open lattice design. The ITI Stent is provided unmounted to be manually crimped onto a noncompliant PTA balloon catheter of choice by the physician. Upon balloon inflation the crimped stent expands to conform to the duct inner luminal surface and retains the expanded state upon balloon deflation.

The intended use is "as a palliative treatment for malignant neoplasms in the biliary tree".

Summary of technological characteristics: both products are balloon expandable stents fabricated by cutting an engineered series of slots/apertures into a 316L stainless steel hypotube. The ITI and predicate stent cuts are made with a laser. Both the ITI and predicate stent are cleaned, electro-polished, packaged in a double sterile barrier and sterilized. The ITI stent is ethylene oxide sterilized and the predicate stent CO_{60}. The ITI and predicate stent are provided unmounted, additionally the predicate stent can be provided premounted on a PTA balloon catheter. For the unmounted stent, the predicate offers a separate non-sterile crimping tool while the ITI product does not. Both the ITI stent and predicate stent include use of manual compression using ones thumbs and forefingers to compress the stent onto the delivery balloon catheter.

K 980290

P2of2

510(k) Summary (Page 2 of 2)

Comparison bench tests regarding performance characteristics were performed on the ITI and predicate stent to demonstrate equivalency. A biocompatibility assessment for cytotoxicity was performed on finished ITI product and determined noncytotoxic. Pyrogenicity testing performed on a lot to lot basis will support the nonpyrogenic claim.

The ITI Stent is substantially equivalent to the currently marketed Cordis Corporation/Johnson & Johnson, legally marketed PALMAZ™ and PALMAZ-SCHATZ™ Balloon-Expandable Biliary Stent as a palliative treatment for malignant strictures of the biliary tree. As demonstrated the ITI Stent is identical in materials, indication for use and technological characteristics. Performance testing (bench) further supports a substantial equivalence claim. The collective evidence therefore provides assurance that the ITI Stent meets the requirements that are considered acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1998

Ms. Amy Peterson
Vice President, RA & QA
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Re: K980290
ITI Biliary Stent
Dated: April 30, 1998
Received: May 1, 1998
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

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 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) 594-4613. 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" (21 CFR 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if know): K980290

Device Name: ITI Stent

Indication For Use:

The ITI Stent is indicated as a palliative treatment for malignant neoplasms in the biliary tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980290

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)