K993904

FEB 1 2000

## 510(k) Summary (Page 1 of 2)

Product Name: IntraStent™ DoubleStrut™ LD
Common Name: Biliary Catheter

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

Official Contact: Cathy Yohnk
Senior Clinical /Regulatory Affairs Specialist
Tel. 651-697-2003 Fax 651-697-2080

Summary Preparation Date: August 19, 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 IntraStent™ DoubleStrut™ LD 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 IntraTherapeutics, Inc. IntraStent™ DoubleStrut™ (K991929) and Cordis Corporation PALMAZ™ and PALMAZ-SCHATZ™ Balloon-Expandable Biliary Stent (K905720, K911581, K964688).

The IntraStent™ DoubleStrut™ LD is a balloon expandable stainless steel stent with an open lattice design. The device is provided unmounted, to be manually crimped onto a noncompliant PTA balloon catheter for biliary stent expansion 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: The IntraStent™ DoubleStrut™ LD provides a larger version the IntraStent™ DoubleStrut™ (K991929), allowing an expanded diameter of 9-12 mm. The IntraStent™ devices are balloon expandable stents fabricated by cutting an engineered series of slots/apertures into a 316L stainless steel hypotube. The cuts are made with a laser. The IntraStent™ devices are cleaned, electro-polished, packaged in a double sterile barrier and sterilized. The IntraStent™ devices are ethylene oxide sterilized and are provided unmounted.

*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.

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The IntraStent™ devices incorporate the use of manual compression using one's thumbs and forefingers to compress the stent onto the delivery balloon catheter.

Bench tests were performed to verify that the IntraStent™ DoubleStrut™ LD met the same performance characteristics as the predicate IntraStent™ DoubleStrut™ (K991929). Pyrogenicity testing performed on a lot to lot basis supports the nonpyrogenic claim.

The IntraStent™ is substantially equivalent to the currently marketed IntraStent™ DoubleStrut™ and the Cordis Corporation/Johnson & Johnson PALMAZ™, and PALMAZ-SCHATZ™ Balloon-Expandable Biliary Stents as a palliative treatment for malignant strictures of the biliary tree. As demonstrated the IntraStent™ DoubleStrut™ LD 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 IntraStent™ 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

FEB 1 2000

Ms. Cathy Yohnk
Senior Clinical Research / Regulatory Affairs Associate
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, Minnesota 55112

Re: K993904
IntraStent™ DoubleStrut™ LD Biliary Stent
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: December 30, 1999
Received: January 3, 2000

Dear Ms. Yohnk:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993904

Device Name: IntraStent™ DoubleStrut™ LD Biliary Stent

FDA's Statement of the Indications For Use for device:

The IntraStent™ DoubleStrut™ LD Biliary Stent is indicated as a palliative treatment for malignant neoplasms in the biliary tree.

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993904