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Premarket Notification (510(k)) Summary

510(k) Number: K003040

Product Name: IntraStent® Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology (Biliary Indication)

Common Name: biliary stent

Class: Class II, 21 CFR 876.5010

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

Official Contact:
Maria Brittle
Sr. Reg/Clin/Training Associate
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Summary Preparation Date: September 28, 2000

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission. Substantial equivalence is claimed to the Cordis S.M.A.R.T. Nitinol Stent Transhepatic Biliary System (K994068).

The IntraStent® Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology is intended as a palliative treatment of malignant neoplasms in the biliary tree.

The Protégé™ stent is a self-expanding nitinol (nickel-titanium alloy) stent provided in multiple lengths, (20, 30, 40, 50, 60, 70 and 80 mm) and diameters (6, 7, 8 and 9 mm). The stent is electropolished. The stent is premounted on an 80 or 120 cm working length 7F, 0.035" over-the-wire delivery catheter designed for transhepatic access. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency in the biliary ducts. The disposable StarPort Delivery Technology system is comprised of an inner and outer sheath, which are locked together with a safety lock.

Biocompatibility testing meeting FDA's "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents" (2/98) was provided. Comparison bench tests regarding performance characteristics were performed on the Protégé and predicate devices to demonstrate equivalency.

The IntraStent® Protégé™ Self-expanding Nitinol Stent with StarPort™ Delivery Technology is substantially equivalent to the currently marketed Cordis S.M.A.R.T. Nitinol Stent Transhepatic Biliary System (K994068) in intended use, materials, technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 2000

Ms. Maria E. Brittle
Senior Reg/Clin/Training Associate
IntraTherapeutics, Inc.
651 Campus Drive
ST. PAUL MN 55112

Re: K003040
IntraStent® Protégé™ Self-Expanding Nitinol Stent with
StarPort™ Delivery Technology (Biliary Indication)
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: September 28, 2000
Received: September 29, 2000

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 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.

510(k) Number (if known): K003040

Device Name: IntraStent® Protégé™ Self-Expanding Nitinol Stent with StarPort™ Delivery Technology (Biliary Indication)

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

The IntraStent® Protégé™ Self-Expanding Nitinol Stent with StarPort™ Delivery Technology (Biliary Indication) is intended as a palliative treatment of malignant neoplasms in the biliary tree.

(Division Sign-Off) ACTING
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003040

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