510(K) SUMMARY

SUBMITTER INFORMATION

A.	Company Name:	IntraLuminal Therapeutics, Inc.
B.	Company Address:	6354 Corte Del Abeto – Suite A Carlsbad, CA 92009
C.	Company Phone:	(760) 918-1820
D.	Company Facsimile:	(760) 603-9615
E.	Contact Person:	Pamela Misajon Vice President of Regulatory Affairs and Quality Assurance

DEVICE IDENTIFICATION

A.	Device Trade Name:	Safe-Cross® Deflecting Catheter (0.018")
B.	Catalog Number:	C118ND1
C.	Device Common Name:	Support Catheter
D.	Classification Name:	Percutaneous Catheter
E.	Device Class:	Class II (per 21 CFR 870.1250)

IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the 0.014" Safe-Cross Deflecting Catheter, manufactured by IntraLuminal Therapeutics and cleared under Premarket Notification 510(k) K032784.

DEVICE DESCRIPTION

The 0.018" Safe-Cross Deflecting Catheter is a coaxial lumen intravascular catheter coated with a Biocoat Hydak® hydrophilic coating intended for percutaneous use. It is designed to be used in conjunction with guide wires to gain access to and facilitate placement of the wires in locations within the vascular system that are remote from the site of insertion. Once accessed, guide wires may be exchanged within the catheter. The Safe-Cross® Deflecting Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

The effective length of the 0.018" Safe-Cross Deflecting Catheter is 135cm. The shaft deflecting segment maximum outside diameter is 4.3Fr at a use pressure of 10atm. The

I.D. at the tip of the Safe-Cross Deflecting Catheter is a nominal 0.022" and the inside diameter will accommodate commercially available 0.018" guidewires.

The 0.018" Safe-Cross Deflecting Catheter is packaged in a Tyvek® covered custom PETG tray that is heat-sealed to form a sterile barrier. The packaged units are sterilized with ethylene oxide gas. The device is provided "STERILE", "Non-Pyrogenic" and is intended for single use only.

INTENDED USE

The Safe-Cross Deflecting Catheter is indicated for use with a guide wire in order to access discreet regions of the peripheral vasculature and facilitate placement of the guide wire. Once the region has been accessed, an exchange of one guide wire for another can occur. The Safe-Cross Deflecting Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TECHNOLOGICAL CHARACTERISTICS

The 0.018" Safe-Cross® Deflecting Catheter is similar in basic materials, design, construction and mechanical performance to the predicate device. The guidewire lumen and outside diameter have been increased to be compatible with commercially available 0.018" guidewires.

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility and performance testing indicate that the 0.018" Safe-Cross Deflecting Catheter satisfies safety and performance requirements of the device specifications and do not raise additional safety issues.

CONCLUSIONS DRAWN FROM STUDIES

On the basis of the testing conducted on the 0.018" Safe-Cross Deflecting Catheter it may be concluded that the device satisfies safety and performance requirements when used in accordance with the Instructions for Use for the indicated patient population. The 0.018" Safe-Cross Deflecting Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2004

IntraLuminal Therapeutics, Inc.
c/o Pamela Misajon
Vice President of Regulatory Affairs and Quality Assurance
6354 Corte del Abeto, Suite A
Carlsbad, Ca 92009

Re: K040481
ILT 0.018" Safe-Cross® Deflecting Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 24, 2004
Received: February 25, 2004

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K040481

Device Name: Safe-Cross® Deflecting Catheter (0.018")

Indications For Use: **The ILT Safe-Cross® Deflecting Catheter is indicated to be used in conjunction with a steerable guide wire in order to access discrete regions of the vasculature. Once the region has been accessed, an exchange of one guide wire for another can occur. The Deflecting Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mc Nemar
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040481