K033708

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® Radio Frequency Total Occlusion Crossing System
C.	Device Common Name:	Catheter Guide Wire
D.	Classification Name:	Catheter Guide Wire
E.	Device Class:	Class II (per 21 CFR 870.1330)

IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the Safe-Cross Radio Frequency Total Occlusion Crossing System, manufactured by IntraLuminal Therapeutics and cleared under Premarket Notification 510(k) K031842.

DEVICE DESCRIPTION

The Safe-Cross Radio Frequency Total Occlusion Crossing System consists of the following:

- 0.014" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer)
- 0.035" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer)
- Safe-Cross RF System Console

The modified Safe-Cross RF System is similar to the predicate Safe-Cross System. The proximal end of the Crossing Wire is connected to a Y-Site hub that houses the optic fiber connector and the RF connector. The optical connector is connected to the OCR

K033708

input on the console to allow the medical practitioner to visualize structures within the vessel for navigation purposes. The RF connector is connected to the RF output on the console. This allows the medical practitioner to provide discrete RF energy to the distal tip to assist in moving the wire tip through the occlusion in the vessel.

The RF Crossing Wire is packaged in a Tyvek® sealed plastic tray. The packaged RF Crossing Wire is provided "STERILE" (ethylene oxide) and non-pyrogenic, and is intended for single use only.

INTENDED USE

The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in vascular interventions of total occlusions in native iliac and superficial femoral arteries (SFA) of the lower extremities.

TECHNOLOGICAL CHARACTERISTICS

The components of the Safe-Cross System are similar in basic materials, design, construction and performance to the predicate device. The RF Generator and OCR Unit have been combined into a single console. The performance of the modified Safe-Cross System has been verified through software testing and bench testing.

PERFORMANCE DATA

In vitro bench testing was conducted to evaluate the performance characteristics of the modified Safe-Cross System. Benchtop performance test results indicate that the components of the Safe-Cross System satisfy 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 modified Safe-Cross System 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 modified Safe-Cross System 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

DEC 11 2003

Intraluminal Therapeutics, Inc.
c/o Ms. Pamela Misajon
6354 Corte Del Abeto, Suite A
Carlsbad, CA 92009

Re: K033708
Safe-Cross® Radio Frequency Total Occlusion Crossing System [Peripheral]
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II (two)
Product Code: DQX
Dated: November 25, 2003
Received: November 26, 2003

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,

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

Enclosure

INDICATIONS FOR USE

510(k) Number: K033708

Device Name: Safe-Cross® Radio Frequency Total Occlusion Crossing System

Indications For Use: **The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in vascular interventions of total occlusions in native iliac and superficial femoral arteries (SFA) of the lower extremities.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-off)
Division of Cardiovascular Devices

510(K) Number K033708 (SM. K)