# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

## SUBMITTER INFORMATION


| | | |
|---|---|---|
| A. | Company Name: | IntraLuminal Therapeutics, Inc |
| B. | Company Address: | 6354 Corte del Abeto<br>Suite A<br>Carlsbad, CA 92009 |
| C. | Company Phone: | (760) 918-1820 |
| D. | Company Facsimile: | (760) 918-1823 |
| E. | Contact Person: | Pamela Misajon<br>Vice President of Regulatory Affairs and Quality Assurance |


## DEVICE IDENTIFICATION

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|---|---|---|
| A. | Trade Name: | ILT Advancing Mechanism |
| B. | Catalog Number: | A115AM1 |
| C. | Common Name: | Advancing Mechanism |
| D. | Classification Name: | Percutaneous Catheter Accessory |
| E. | Device Class: | Class II (per 21 CFR 870.1250) |

## IDENTIFICATION OF PREDICATE DEVICE

The ILT Advancing Mechanism is similar in design, materials, mode of operation and intended use to the IntraLuminal Therapeutics, Inc. ILT 0.014" Catheter cleared under 510(k) K001992 and ILT Deflecting Catheter cleared under 510(k) K010531.

## DEVICE DESCRIPTION

The ILT Advancing Mechanism is a detachable handle with a distal luer fitting that can be mated with percutaneous catheters. It is designed to be used in conjunction with percutaneous catheters and steerable guide wires to gain access to locations within the cardiovascular structure that are remote from the site of the insertion. Once accessed, the Advancing Mechanism can incrementally advance or retract the steerable guide wire in an occlusion.

The Advancing Mechanism is approximately five inches in length and can be operated with one hand. When the Advancing Mechanism is engaged, each click of the handle

advances or retracts the guide wire an average of 0.26 ± 0.05mm. This mechanism can be disengaged (bypassed) for free movement of the guide wire within the attached catheter.

The ILT Advancing Mechanism is packaged in a Tyvek®/mylar pouch 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 Advancing Mechanism is indicated for use with a guide wire in order to access discreet regions of the vasculature. Once the region has been accessed, the Advancing Mechanism can incrementally advance or retract the guide wire in an occlusion.

## TECHNOLOGICAL CHARACTERISTICS

The ILT Advancing Mechanism is similar in basic materials, design, construction and mechanical performance to the predicate device.

## BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing and *in vivo* bench studies were conducted to evaluate the biological and performance characteristics of the ILT Advancing Mechanism. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

## CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the ILT Advancing Mechanism is substantially equivalent to the predicate devices and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2002

IntraLuminal Therapeutics, Inc.
Ms. Pamela Misajon
Vice President of Regulatory Affairs and
Quality Assurance
6354 Corte del Abeto, Suite A
Carlsbad, CA 92009

Re: K021638
ILT Advancing Mechanism
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire.
Regulatory Class: Class II (two)
Product Code: 74 DQX
Dated: May 17, 2002
Received: May 20, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

**510(k) Number:** K021638

**Device Name:** ILT Advancing Mechanism

**Indications for Use:** The ILT Advancing Mechanism is indicated for use with a guide wire in order to access discreet regions of the vasculature. Once the region has been accessed, the Advancing Mechanism can incrementally advance the guide wire.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K021638