PATHWAY
MEDICAL TECHNOLOGIES

JUL 17 2008

SECTION 5: 510(k) SUMMARY

In accordance with the requirements of 21 CFR 807.92(c) Pathway Medical Technologies, Inc. (hereafter "Pathway Medical") has prepared this 510(k) Summary to provide information supporting the substantial equivalence of the Pathway PV™ Atherectomy System.

General Information:

Date of Summary Preparation:	May 9, 2008
Name and Address of Manufacturer:	Pathway Medical Technologies, Inc. 10801 120th Ave NE Kirkland, Washington 98033
Contact Person:	Brian Cleary Director of Regulatory Affairs Phone: 425-636-4079 Fax: 425-636-4001
Trade Name:	Pathway PV™ Atherectomy System
Common Name:	Peripheral Atherectomy Catheter
Device Classification:	Catheter, Peripheral, Atherectomy
Classification Panel:	Cardiovascular
CFR Reference:	870.4875
Product Code:	MCW
Device Class:	Class II

000018

Predicate Devices: The Pathway PV Atherectomy System is substantially equivalent to the following legally marketed predicate device systems indicated for similar or identical use:

- FoxHollow Technologies Inc. ReFORM Peripheral Catheter System (marketed as the SilverHawk® Plaque Excision System) - K024243, K043553, K053460, K061063, K061188
- Boston Scientific Corporation Rotablator® Rotational Angioplasty System - K901206, K954604, K970296, K993648
- InterVentional Technologies, Inc. Transluminal Endarterectomy Catheter (TEC) - K890515, K922970

Indications for Use: The Pathway PV Atherectomy System is intended for use in atherectomy of the peripheral vasculature. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Device Description: The Pathway PV Atherectomy System consists of two primary components: (1) a PV Catheter and Control Pod and (2) a PV Console, which are packaged separately. Each of these system components is described generally as follows:

- **PV Catheter and Control Pod:** A sterile, single-use unit consisting of an electrically driven PV Catheter and Control Pod. The PV Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities. The Control Pod provides a user interface with keypad controls and LED indicators for device operational status. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double pouched tray.

- **Console:** A reusable compact PV Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PV Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

The Pathway PV Atherectomy System is compatible with 8F sheaths and exchange length (300cm or longer) 0.014" diameter guidewires.

Technological Characteristics: The Pathway PV Atherectomy System's PV Catheter is placed for treatment at the selected peripheral treatment site over a 0.014" exchange length guidewire. All device functions are then controlled by the user via the external handheld Control Pod. The Pathway PV Atherectomy System includes a fluted cutting tip designed with expandable blades. Expandable blade deployment and retraction is controlled by the user.

Separate lumens within the PV Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the treatment site through ports in the PV Catheter tip to a collection bag located on the PV Console.

The distal portion of the PV Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

Substantial Equivalence: As compared to the predicate devices, the Pathway PV Atherectomy System has the identical indication for use as the FoxHollow SilverHawk Plaque Excision System and the identical device classification and device code as all of the selected predicate devices. The Pathway PV Atherectomy System is comprised of the same general patient contact materials and has undergone appropriate biocompatibility testing for its intended use. As with all of the listed predicate device systems, the PV Catheter component is provided sterile and is intended for single-use.

With respect to general device design and technological characteristics, the Pathway PV Atherectomy System is substantially equivalent to all of the selected predicate devices, since it similarly uses a cutting tip controlled by an external handheld control unit for the treatment of peripheral vascular lesions. The multilumen catheter design of the Pathway PV Atherectomy System allows for the infusion of sterile saline to the atherectomy treatment site (equivalent to the Boston Scientific Rotablator predicate device) and the removal of tissue and fluid from the patient via vacuum aspiration (equivalent to the IVT TEC predicate device).

There are no significant technological differences among the subject device and the predicate devices. Therefore, the Pathway PV Atherectomy System is substantially equivalent to the predicate devices.

Device Testing: Performance testing of the Pathway PV Atherectomy System included in vitro performance, biocompatibility, packaging, sterilization, electrical/EMC, animal, and clinical study. All testing was completed per Pathway Medical's in-house test methods, protocols, and requirements or in accordance with applicable recognized standards.

Conclusion: The information contained in this 510(k) summary establishes the substantial equivalence between the Pathway PV Atherectomy System and the selected predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2008

Pathway Medical Technologies, Inc.
C/O Brian Cleary
Director of Regulatory Affairs
10801 120th Avenue NE
Kirkland, WA 98033

Re: K081328
Trade/Device Name: Pathway PV Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW
Dated: May 9, 2008
Received: May 12, 2008

Dear Mr. Cleary:

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

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K081328

Device Name: Pathway PV™ Atherectomy System

Indications for Use: The Pathway PV™ Atherectomy System is intended for use in atherectomy of the peripheral vasculature. It is not intended for use in coronary, carotid, iliac or renal vasculature.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marie R. Vidmar

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081328