K082186
p. 1 of 2

510(k) SUMMARY

General Information:

AUG 29 2008

Date of Summary Preparation:	July 31, 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
Regulation Number:	21 CFR 870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class II
Classification Panel:	Cardiovascular
Product Code:	MCW
Predicate Device:	510(k) Number: K081328 Manufacturer: Pathway Medical Technologies, Inc. Trade 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.

Device Description: The Pathway PV Atherectomy System is an atherectomy catheter system designed with an expandable cutting tip for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through ports in the Catheter tip to a collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

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

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

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

This 510(k) is for the same device with modifications to: (1) the Catheter and Control Pod to improve the manufacturability of the device, and (2) the Control Pod and Console for improved ergonomics and ease of use.

Substantial Equivalence: The Pathway PV Atherectomy System is substantially equivalent to the specified predicate device. The device has the identical indications for use and the same technological characteristics. Bench and laboratory testing was completed and provided to support the safety and effectiveness of the modifications that were the subject of this 510(k) for the Pathway PV Atherectomy System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

Pathway Medical Technologies, Inc.
c/o Mr. Brian Cleary
10801 120th Ave NE
Kirkland, WA 98033

Re: K082186
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: July 31, 2008
Received: August 1, 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 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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,

Donna R. Vuchinich

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): K 082186

Device Name: Jetstream 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)

Donna R. Vochney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082186