510(k) SUMMARY

Submitter Name:	Path Scientific, LLC
Contact Person:	T.R. Gowrishankar, Ph.D.
Address:	82 Hillside Drive Carlisle, MA 01741
Phone Number:	978-369-7315
Fax Number:	978-369-7325
Date Prepared:	September 30, 2005
Device Trade Name:	**PathFormer**
Classification Names,	Surgical Instrument Motors and Accessories/Attachments
Classification #	21 CFR 878.4820
Predicate Devices:	Donald C. Hugh, DDS, NAILeezer First Aid Manual Trephinating Drill
Device Description:	The Path Scientific, LLC. PathFormer is a battery-powered hand-held drill that cuts holes in fingernails and toenails using mesoscissioning technology. It cuts the nail with a microcutting tool, using skin impedance as the feedback mechanism for stopping the cutting intervention.
Intended Use:	The PathFormer device is intended for use in relieving pressure from subungual hematomas (including black toe). It cuts through finger and toe nails to release fluid accumulated in the underlying nail bed.
Discussion of tests and test results:	A variety of tests to fully demonstrate the PathFormer's mechanical, electrical, safety and performance characteristics have been provided in the 510(k) documentation.
Conclusion:	The testing reported in this 510(k) establishes the device is safe and effective for its intended use and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2005

Path Scientific, LLC
c/o Patsy J. Trisler, J.D., RAC
Regulatory Consultant
Regulatory & Clinical Compliance Consulting -Medical Devices-
5600 Wisconsin Avenue #509
Chevy Chase, Maryland 20815

Re: K052770
Trade/Device Name: PathFormer
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: I
Product Code: NWF
Dated: September 30, 2005
Received: September 30, 2005

Dear Ms. Trisler:

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 (240) 276-0115. 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/industry/support/index.html

Sincerely yours,

for Barbara Buehler

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052770

Device Name: PathFormer

Indications for Use:

The PathFormer device is intended for use in relieving pressure from subungual hematomas (including black toe). It cuts through finger and toe nails to release fluid accumulated in the underlying nail bed.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Barbara Bruchup

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052770