K032105

OCT 3 0 2003

510(k) Summary

General Information

Classification	Class II
Trade Name	EndoHelix™ Endarterectomy Device
Submitter	ENDARx Inc. 3270 Alpine Road Portola Valley, CA 94028 650-926-9335
Contact	Scott Adams President

Intended Use

The EndoHelix Endarterectomy Device is intended to remove plaque deposits from arteries.

Predicate Devices

K904944 Transluminal Endarterectomy Device from Baxter Healthcare Corporation

K003719 Periscope Device from Vascular Architects

Device Description

The EndoHelix endarterectomy device is a tubular device with an expanding helical element at the distal tip. The expandable helical element is controlled by the user with a sliding tab on the handle. The device is designed to be used with or without a guidewire.

The device is packaged in an industry standard Tyvek/Mylar pouch and is provided sterile. The EndoHelix device is a single use product and is not intended to be resterilized or reused.

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Materials

All materials used in the manufacture of the EndoHelix Endarterectomy Device are suitable for this use and have been used in numerous previously cleared products.

Testing

Testing was performed to assess product compliance with the product specification. Testing included device operation, wire actuation, and bond pull strengths.

All product met specification.

Summary of Substantial Equivalence

The EndoHelix Endarterectomy Device is equivalent to the predicate devices. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. ENDARx Inc. believes the EndoHelix Endarterectomy Device is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

EndarX, Inc.
c/o Mr. J. Scott Adams
3270 Alpine Road
Portola Valley, CA 94028

Re: K032105
EndoHelix™ Endarterectomy Device
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: DWX
Dated: October 20, 2003
Received: October 22, 2003

Dear Mr. Adams:

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) 594-4646. 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) you may obtain. 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,

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

Enclosure

K032105

Indications for Use

510(k) Number (if known):	This application
Device Name:	EndoHelix™ Endarterectomy Device
Indications for Use:	The EndoHelix Endarterectomy Device is intended to remove plaque deposits from arteries.

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) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032105