SEP 1 6 2003

AKónya Eliminator™ Mechanical Thrombectomy Device
510(k) Summary

Submitter: IDev Technologies, Inc.
1110 NASA Road One, Suite 311
Houston, Texas 77058

Contact Person: Ms. Lynne A. Davies
Regulatory Affairs Manager
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Date Prepared: February 17, 2003

Trade Name: AKónya Eliminator™ Mechanical Thrombectomy Device

Common Name: Thrombectomy Catheter

Classification Name: Catheter, Peripheral, Atherectomy (21 CFR 870.4875)

Product Code: MCW

Predicate Device: Arrow-Trerotola ™ Percutaneous Thrombolytic Device (PTD) (K970080, K990829)

Device Description:

The AKónya Eliminator™ Mechanical Thrombectomy Device is comprised of three discrete elements:

- An outer member, connected distally to the proximal end of the thrombasket. The proximal end is connected to a hemostasis Y-connector, having a side port for flushing, and a Tuohy-Borst connector on the central port for securing to hypotube, as an aid for handling during the surgical procedure.
- An inner member, connected distally to the distal end of the thrombasket. Proximally, the inner member is connected to a handle.
- A thrombasket, composed of woven or braided stainless steel wire.

Intended Use:

The AKónya Eliminator™ Mechanical Thrombectomy Device is indicated for use in the mechanical declotting of synthetic dialysis grafts.

Technological Characteristics Compared to Predicate:

IDev Technologies, Inc. considers the AKónya Eliminator™ as substantially equivalent to the Arrow-Trerotola™ PTD as listed in the following:

- Indication
- Size
- Proximal
  - drive mechanism
  - contrast port
- Distal
  - basket radiopaticity
  - working profile
  - basket diameter
  - basket diameter variability
  - mechanism of action
  - soft distal tip

Non-clinical Performance Testing:

The AKónya Eliminator™ Mechanical Thrombectomy Device has successfully passed all functional and safety testing requirements to ensure substantial equivalence to the predicate device. The testing is described below:

- Accelerated Aging / Packaging - to determine effects of time & environment on device and packaging materials, to substantiate 1-year shelf life. Tests include package Seal Peel, Burst, Dye Penetration, and device functionality after aging.
- Packaging / Shipping Integrity - to determine possible adverse effects of shipping & transportation environments on survivability of device packaging and construction materials.
- Dimensional / Flexibility / Pushability - to evaluate and compare in a quantitative manner pushability and trackability of AKónya Eliminator design to the predicate device and to insure that the device met dimensional requirements, as defined in the product specification.
- Tensile - to verify AKónya Eliminator design meets minimum tensile strength requirements at all joints, as defined in product specification.
- Fatigue - to determine the fatigue life of the AKónya Eliminator.
- Biocompatibility - to determine the potential toxicity resulting from contact of the component materials of the device with the body.
- Animal Study - to evaluate the safety and efficacy of a proposed AKónya Eliminator™, and evaluate operational characteristics of the device with respect to utilization of a predicate device.

Conclusion:

IDev Technologies, Inc. considers the AKónya Eliminator™ Mechanical Thrombectomy Device to be substantially equivalent to the Arrow-Trerotola ™ Percutaneous Thrombolytic Device based on design and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2003

IDev Technologies Inc.
c/o Lynne A. Davies
Regulatory Affairs Manager
1110 NASA Road One, Suite 311
Houston, TX 77058

Re: K030504
Trade/Device Name: AKonya Eliminator™ Mechanical Thrombectomy Device
Regulation Number: 21 CFR 870.4875
Regulation Name: Intralumnial artery stripper.
Regulatory Class: Class II
Product Code: MCW
Dated: June 17, 2003
Received: June 18, 2003

Dear Ms. Davies:

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) 594-4536. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K030504

Indications for Use Statement

Applicant: IDev Technologies, Inc.

510(k) Number (if known): unknown

Device Name: AKónya Eliminator™ Mechanical Thrombectomy Device

Indications for Use: The AKónya Eliminator™ Mechanical Thrombectomy Device is indicated for use in the mechanical declotting of synthetic dialysis grafts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K030504