October 8, 2021

Idev Technologies, Inc.
Shannon Hurd
Regulatory Affairs Manager
1110 Nasa Rd., Suite 311
Houston, Texas 77058-3345

Re: K041374
Trade/Device Name: Akonya Eliminator Plus Mechanical Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA

Dear Shannon Hurd:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 02, 2005. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.08 10:26:22 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 - 2005

Idev Technologies, Inc.
c/o Ms. Shannon Hurd
Quality Manager
1110 NASA Road, Suite 311
Houston, TX 77058

Re: K041374
Trade Name: AKonya Eliminator Mechanical Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: February 24, 2005
Received: February 25, 2005

Dear Ms. Hurd:

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) 276-0120. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): ***K041374***

Device Name: ***AKónya Eliminator Plus™ Mechanical Thrombectomy Device***

Indications For Use: ***The AKónya Eliminator Plus™ Mechanical Thrombectomy Device is indicated for use in the mechanical declotting native arterio-venous (AV) fistula and synthetic dialysis grafts.***

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechmey

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041374

K 041374

MAR 2 - 2005

510(k) Summary

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

Contact Person: Ms. Shannon Hurd
Quality Manager
(281) 333-1998 x 224 – Phone
(281) 333-4008 – Fax
BACKUP:
Mr. Jeffery Sheldon
President & CEO
(281) 333-1998 x 228 – Phone
(281) 333-4008 – Fax

Date Prepared: November 19, 2004

Trade Name: AKónya Eliminator Plus™ Mechanical Thrombectomy Device

Common Name: Thrombectomy Catheter

Classification Name: Catheter, Embolectomy (21 CFR 870.5150)

Product Code: DXE

Predicate Device:
- AKónya Eliminator™ Mechanical Thrombectomy Device (K030504)
- Arrow-Trerotola ™ Percutaneous Thrombolytic Device (PTD) (K011056)

Device Description:

The AKónya Eliminator Plus™ 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 Plus™ Mechanical Thrombectomy Device is indicated for use in the mechanical declotting native arterio-venous (AV) fistula and synthetic dialysis grafts.

Technological Characteristics Compared to Predicate:

The AKónya Eliminator Plus™ has the same technological characteristics as the predicate devices.

Non-clinical Performance Testing:

The expanded indication for use to include native arterio-venous (AV) fistula is based on the pre-clinical animal data presented in the performance section of this 510(k) submission.

Conclusion:

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