October 8, 2021

Xtrak Medical Inc.
Debbie Iampietro
President
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K021641
Trade/Device Name: XTD Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW

Dear Debbie Iampietro:

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 July 26, 2002. Specifically, FDA is updating this SE Letter 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 10:19:03 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
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

JUL 2 6 2002

XTRAK Medical, Inc.
Ms. Debbie Iampietro
c/o QRC Consulting Associates
7 Tiffany Trail
Hopkinton, MA 01748

Re: K021641
Device Name: XTD™ Thrombectomy Cathater
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: July 2, 2002
Received: July 2, 2002

Dear Ms. Iampietro:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: XTRAK MEDICAL, INC.

510(k) Number (if known): _____

Device Name: XTD™ Thrombectomy Catheter

Indications For Use:

For breaking apart and removing thrombus from hemodialysis access grafts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021641

Prescription Use X
(Per 21 CFR 801.109)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
XTD™ Thrombectomy Catheter
July 1, 2002

General Information

Classification:	Class II
Trade Name:	XTD™ Thrombectomy Catheter
Sponsor:	Xtrak Medical, Inc. 26H Keewaydin, Dr. Salem, NH 03079 Tel: (603) 896-6416 Fax: (603) 893-7708
Contact:	Gary Boseck, Ph.D. President

Identification of Predicate or Legally Marketed Devices

The XTD™ Thrombectomy System (K013473) manufactured by Xtrak Medical, Inc.

Intended Use

For breaking apart and removing thrombus from hemodialysis access grafts.

Device Description

The XTD™ Thrombectomy Catheter is a sterile, single-use, disposable catheter designed to simultaneously fragment and remove thrombus from clotted hemodialysis access grafts. The catheter consists of a flexible, spiral-conveyor shaft rotating within a plastic sheath. The shaft has a small, flexible, curved agitator which extends out of the sheath. As the agitator rotates it breaks the thrombus to particles. The particles are aspirated into the sheath and are conveyed by the rotating spiral shaft through the sheath to a collection line connected to a disposable vacuum syringe. A pinch clamp on the collection line isolates the syringe and allows the operator to manually control the delivery of suction to the catheter tip. The battery supply and a luer connection for the syringe are incorporated directly onto the catheter.

Materials

All materials used in the manufacture of the XTD™ Thrombectomy Catheter are suitable for their intended use and are used commonly in the manufacture of previously cleared products.

Performance Testing

The XTD™ Thrombectomy Catheter components have been tested to assess compliance with their specifications and to support claims of substantial equivalence to the predicate device. This testing includes the following:

Mechanical Bench Testing
Battery Life Testing
Electrical Safety Testing
Electrical Emissions Testing
Ship Testing

Test results have demonstrated conformance of the XTD™ Thrombectomy Catheter to its specification requirements, and that the XTD™ Thrombectomy Catheter is as safe and effective as the legally marketed predicate device.

Summary of Substantial Equivalence

Xtrak Medical believes that the XTD™ Thrombectomy Catheter is substantially equivalent to the legally marketed predicate device. This claim of equivalence is supported by the identical intended use of the devices and their common fundamental scientific characteristics.