K013473

MAR 6 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

XTD™ Thrombectomy System
Xtrak Medical, Inc.
January 17, 2002

General Information

Classification:	Class II
Trade Name:	XTD™ Thrombectomy System
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
Possis AngioJet Rapid Thrombectomy System (K960970), manufactured by Possis Medical, Inc., and Arrow-Trerotola Percutaneous Thrombolytic Device (K970080), manufactured by Arrow International, Inc.

Intended Use
For breaking apart and removing thrombus from hemodialysis access grafts.

Device Description
The XTD™ Thrombectomy System consists of the XTD™ Thrombectomy Catheter, XTD™ Control Console, and XTD™ Collection Bottle units. The XTD™ catheter has a flexible, rotating spiral conveyor shaft contained within a 6F plastic sheath. The distal end of the spiral shaft extends from the sheath as a curved flexible agitator. As the agitator rotates it macerates thrombus within the graft and the rotating spiral conveyor shaft conveys the macerated thrombus through the sheath, assisted by negative pressure, to a disposable Collection Bottle. The Control Console provides the suction and battery power required for catheter operation.

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

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

- Mechanical Strength Testing
- Fatigue Strength Testing
- Electrical Safety Testing
- Biocompatibility Testing
- In-vitro Performance Testing
- In-vivo (animal) Testing
- Human Clinical Testing

Test results have demonstrated conformance of the XTD™ components to their specification requirements, and that the XTD™ Thrombectomy System is as safe and effective as the legally marketed predicated devices.

Summary of Substantial Equivalence

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2002

Xtrak Medical, Inc.
c/o Gary Boseck, Ph.D.
26H Keewaydin Dr
Salem, NH 03079

Re: K013473
XTD™ Thrombectomy System
Regulation Number: 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: II (two)
Product Code: MCW
Dated: January 17, 2002
Received: January 18, 2002

Dear Dr. Boseck:

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) 594-4586. 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,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory 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): K013473

Device Name: XTD™ Thrombectomy System

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)

Division of Cardiovascular & Respiratory Devices (Per 21 CFR 801.109)

510(k) Number K013473

(Optional Format 1-2-96)