K032660

OCT 2 9 2003

510(k) Summary

General Information

Classification:	Class II (per 21 CFR 870.1250)
Trade Name:	Xtrak Support Catheter
Sponsor:	Xtrak Medical, Inc. 26H Keewaydin, Dr. Salem, NH 03079 Tel: (603) 896-6416 Fax: (603) 893-7708
Contact:	Gary Boseck, Ph.D.

Identification of Predicate or Legally Marketed Devices:
ILT Safe Cross Support Catheter (K030984) manufactured by Intraluminal Therapeutics, Inc.

Intended Use:
The Xtrak Support catheter is intended to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature.

Device Description:
The Xtrak Support catheter shaft consists of a flexible, distal section made of closely-wound coils, and a stiffer and more torqueable mid-section coupled to a proximal handle through a short length of spiraled strain relief. The distal and mid-shaft sections, and the strain relief are constructed from a continuous length of stainless steel wire to maximize catheter integrity. The catheter is provided in various sizes to accommodate .014" and .018" guidewires.

Materials:
All materials used in the manufacture of the Xtrak Support catheter are suitable for their intended use and are used commonly in the manufacture of previously cleared products.

Performance Testing:
The Xtrak Support catheter 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
- Biocompatibility Testing

Test results demonstrate conformance of the Xtrak Support catheter components to their specification requirements, and that the Xtrak Support catheter is as safe and effective as the legally marketed predicated devices.

Summary of Substantial Equivalence:
Xtrak Medical believes that the Xtrak Support catheter 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

OCT 2 9 2003

Xtrak® Medical, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
26H Keewaydin Dr.
Salem, NH 03079

Re: K032660
Trade Name: Xtrak® Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 26, 2003
Received: September 3, 2003

Dear Ms. Iampietro:

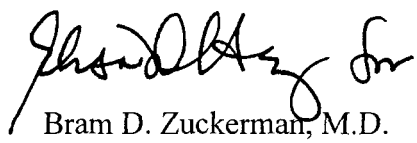
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is,substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), please contact the Office of Compliance at (301) 594-4646. 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

Ver/ 3 - 4/24/96

Applicant: XTRAK MEDICAL, INC.

510(k) Number (if known): K032660

Device Name: Xtrak Support Catheter

Indications For Use:

The Xtrak Support Catheter is intended to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number K032660

Prescription Use
(Per 21 CFR 801.109)

Prescription Use X 10/28/03
(Per 21 CFR 801.109)