K991647

JAN - 4 2000

# 510(k) Summary

**1. Submitter Name, Address, and Date of Submission.**

Mrs. Julie A. Beaumont
Group Regulatory Affairs Technician
TFX Medical Group
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6179
E-Mail: jbeaumont@tfx.com

Contact: Same as above

**2. Name of the Device, Common, Proprietary (if Known), and Classification.**

Classification Name: Introducer Kit

Common Name: TFX Medical Introducer Kit

Proprietary Name: TFX Medical Introducer Kit

**3. Identification of the legally marketed device to which the submitter claims equivalence.**

The TFX Medical Introducer Kit is substantially equivalent to the Burron Tear-Away Sheath Introducers and Daig Corporation Introducer Sets.

**4. Description of the Device.**

The TFX Medical Introducer Kit consists of a Sheath/Dilator Assembly, Needle with indicator, Syringe, Guide-wire Tray

## 5. Intended Use of the Device.

This product is to assist in the percutaneous introduction of diagnostic or therapeutic devices into a vessel.

## 6. Summary of Technological Characteristics.

The TFX Medical Introducer Kits are substantially equivalent to the predicate devices, since the basic features, designs and intended uses are the same. The differences between the TFX Medical, Incorporated devices and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2000

Mrs. Julie A. Beaumont
Regulatory Affairs Technician
TFX Medical Inc.
Tall Pines Park
Jaffrey, NH 03452

Re: K991647
Trade Name: TFX Medical Introducer Kit
Regulatory Class: II
Product Code: DYB
Dated: October 29, 1999
Received: November 2, 1999

Dear Mrs. Beaumont:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices

under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991647

Device Name: TFX Medical Introducer Kit

Indications for Use:

This product is to assist in the percutaneous introduction of diagnostic or therapeutic devices into a vessel.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

for Written