K021634
1 of 3

JUN 26 2002

TFX Medical®

510(k) Summary

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

Rick Lykins
Group RA Manager - US
TFX Medical Group
Tall Pines Park
Jaffrey, NH 03452

Telephone: (603) 532-0204
Fax: (603) 532-6179
E-Mail: rlykins@tfx.com

Contact: Same as above

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

Classification Name:	Tube, Gastrointestinal and Accessories
Common Name:	Guidewire Introduction Safety Needle with Introducer
Proprietary Name:	Modified TFX Medical Safety Needle with Introducer

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

The Modified TFX Medical Safety Needle with Introducer is substantially equivalent in design and materials to:

- The TFX Medical Introducer Needle - K851140
- The PUNCTUR-GUARD Blood Collection Needle of Bio-Plexus, Inc, for the activation mechanism - K895034
- The COOK® OB/GYN Russell Gastrostomy Tray - K912047
- TFX Medical, Inc. Over-the-Needle Splitable Catheter Assembly, Type I - K920908

- The TFX Medical Safety Needle with Introducer - K000665
- The COOK® Gastric Port System - 510(k) Unknown
- The COOK® Edelman Gastrostomy Tray - 510(k) Unknown

4. Description of the Device:

This device, with the exception of length, is identical to the TFX Medical Safety Needle with Introducer cleared by the FDA in K000665. The working length of the needle has been increased, due to the intended gastrointestinal use, and will be available in 2F - 6F sizes with lengths ranging between 2.50" - 4.0". The Modified TFX Medical Safety Needle with Introducer will allow placement of guidewires ranging from 0.015" - 0.052". The variance in sizes and lengths is due to specific procedure, physician preference and patient body type.

This product consists of two components:

1. Safety Needle (Needle with Passive Sharps Protection)- The Safety Needle, which has the same blunter technology as the Bio-Plexus, Punctur-Guard® Blood Collection needle, is manufactured under the QSR Design Control requirements. The guidance document, "Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Protection Features", was used in the design and verification of the function of the Safety Needle.

2. Peelable Splitable Introducer- This introducer is identical to the existing introducer sold by TFX Medical, which was cleared under K920908.

5. Intended Use of the Device:

The TFX Medical Safety Needle with Introducer is intended to be used for guidewire introduction during gastrointestinal procedures such as PEG (Percutaneous Endoscopic Gastrostomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.

6. **Summary of Technological Characteristics:**

The Modified TFX Medical Safety Needle with Introducer adds a safety feature to the needle for the prevention of needle sticks, after the needle is withdrawn from the hub of the introducer.

The device is equivalent technologically to the devices mentioned on pages 1-2. The anti-stick safety feature, which forms an integral part of this device, is the reason for this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Mr. Rick Lykins
Group RA Manager – US
TFX Medical Group
Tall Pines Park
JAFFREY NH 03452

Re: K021034
Trade/Device Name: Modified TFX Medical Safety Needle with Introducer
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: March 28, 2002
Received: March 29, 2002

Dear Mr. Lykins:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021034

Device Name: Modified TFX Medical Safety Needle with Introdfucer

Indications for Use:

The Modified TFX Medical Safety Needle with Introducer is intended to be used for guidewire introduction during gastrointestinal procedures such as PEG (Percutaneous Endoscopic Gastrostomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Broadon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021034