Teleflex MEDICAL

FEB 2 1 2013

510(K) SUMMARY

1. SUBMITTER:

Manufacturer:

Teleflex Medical
50 Plantation Drive
Jaffrey, NH 03452
Telephone #(603) 532-7706
Establishment Registration Number: 1221019

Owner/Operator:

Teleflex Medical
2917 Weck Drive
Research Triangle Park, NC 27709
Owner/Operator #9062981

Official Contact:

Dawn I. Moore	Regulatory Affairs Manager
Telephone:	734-368-2214
Date Prepared:	December 20, 2012

2. DEVICE:

Tradename:	Percutaneous Introducer and Kit
Classification Name:	Introducer, Catheter
Classification:	Class II
Common Name:	Introducer Kit
Classification Panel:	Cardiovascular
Product Code:	DYB
Regulation Number:	870.1340

3. PREDICATE DEVICES:

- Teleflex Percutaneous Introducer cleared under 510(k) Premarket Notification #K060519
- Greatbatch Medical PTFE Peelable Introducer Kit cleared under 510(k) Premarket Notification #K102540.

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4. DEVICE DESCRIPTION:

Teleflex Medical OEM's Percutaneous Introducer and Kit is used to assist in the introduction of diagnostic or therapeutic devices into a vessel. These devices will be marketed in two configurations:

- Percutaneous Introducer only, or
- Introducer Kit including Percutaneous Introducer, Needle, Syringe and Guidewire

A description of each individual component is provided below:

Guidewire
The guidewire is designed to allow ease of movement through the vessels of the body.

18 Ga Needle
The 18 Ga Needle design allows the syringe to be attached to it and for the guidewire to be inserted through it.

Syringe
The 10ml syringe design allows for insertion into the needle.

Percutaneous Introducer
The Percutaneous Introducer uses a secure locking luer collar hub design and also incorporates an ergonomic handle design. This protects against separation of the dilator and sheath assembly during insertion. The introducer is designed to allow the dilator to be advanced over the guidewire into the vessel thus facilitating the introduction of the sheath into the vessel. This device design is such that after advancement into the vessel the dilator can be removed to allow access through the sheath of the customer's chosen device. For easy removal, the split sheath can be removed by breaking the hub and removing the two halves of the sheath while still within the vessel. The sheath hub is designed to snap cleanly. The sheath peels easily and evenly, thus reducing complications during the procedure.

5. INDICATIONS FOR USE:

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

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6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Comparisons of the proposed and predicate devices show that the technological characteristics such as intended use, materials, kit components, performance characteristics and packaging are identical or substantially equivalent to the currently marketed predicate devices.

7. NONCLINICAL PERFORMANCE DATA:

The Percutaneous Introducer and Kit was subjected to a full battery of performance testing including pre-determined acceptance criteria. As expected, the device met all acceptance criteria. The results of the performance testing (i.e., dimensional, tensile, radiopacity, corrosion resistance, leakage, etc.) demonstrate that these devices are substantially equivalent to the currently marketed predicate devices, adequately meets their intended use, and are acceptable for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Teleflex Medical
Dawn Moore, Regulatory Affairs Manager
50 Plantation Drive
Jaffrey, NH 03452

Re: K123974
Trade/Device Name: Percutaneous Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: December 20, 2012
Received: December 26, 2012

Dear Ms. Moore:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K123974

Device Name: Percutaneous Introducer and Kit

Indications for Use:

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

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner