APR 17 2014

2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: September 5, 2013

510(k) Number: K132789

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Ellie Gillespie
Sr. Regulatory Product Specialist
Tel: 763-656-4300
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General Information

Trade Name	Flip Introducer access kit
Common / Usual Name	access kit
Classification Name	870.1340, DYB – Catheter introducer, Class II
Predicate Device	K082644 – Glidesheath introducer sheath (Terumo Corporation)

Device Description

The Flip Introducer access kit is used to gain vascular access and allow placement of a guide catheter (not included). The Flip Introducer access kit contains the following components:

- 21G x 4 cm percutaneous entry needle
- 0.018" x 180 cm guidewire with a Nitinol mandrel and curved tungsten tip
- Flip Introducer

The Flip Introducer functions as a dilator to gain vascular access, allowing sheathless delivery of a guide catheter into a vein or artery to perform a percutaneous catheterization procedure. The Flip Introducer consists of a hollow PEEK extruded tube with a tapered distal end that has a radiopaque marker band and a hydrophilic-coated Pebax funnel. A tuohy borst is provided on the proximal end of the device. The Flip Introducer is 130 cm long and compatible with 0.018" guidewires. The Flip Introducer is available in two sizes for use with 6F and 7F guide catheters.

Intended Use / Indications

The Flip Introducer access kit is used to facilitate placing a guide catheter through the skin into a vein or artery, including but not limited to the radial artery.

Technological Characteristics

The Flip Introducer is similar in design to the predicate device as they are both single lumen dilators that are used to gain vascular access. Both the subject and predicate devices have tapered distal tips and hydrophilic coating. The Flip Introducer has a polymer cuff that covers the distal tip of the guide catheter during insertion to allow sheathless insertion of the guide catheter.

Substantial Equivalence and Summary of Studies

Technological differences between the subject and predicate device have been evaluated through biocompatibility and mechanical tests to provide evidence of safe and effective use of the Flip Introducer. The Flip Introducer is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use.

The subject device design has been verified through the following mechanical tests:

- Fluoroscopy visualization
- Dilator length
- Dilator shaft OD
- Dilator/guidewire compatibility
- Dilator insertion force
- Dilator prolapse
- Dilator bond strength

The following biocompatibility tests were performed as recommended by ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility

Verification test results met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Flip Introducer is substantially equivalent to the predicate device.

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

April 17, 2014

Vascular Solutions, Inc.
Ellie Gillespie
Senior Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K132789
Trade/Device Name: Flip Introducer access kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 10, 2014
Received: April 11, 2014

Dear Ms. Gillespie:

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 contact 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. 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,

Bram D. Zuckerman -S

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Flip Introducer access kit

Indications for Use:

The Flip Introducer access kit is used to facilitate placing a guide catheter through the skin into a vein or artery, including but not limited to the radial artery.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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