

K 092629

Section 14: Special 510(k) Summary



SEP 25 2009

Special 510(K) Summary
For SNM Firmgrip™ Peripherally Inserted Catheter Device
**SNM - Safety Needle Mechanism*

Date Prepared: 24 August, 2009

510(k) owner name:

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Contact person:

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Device Name:

Common or usual name: Peripherally Inserted Catheter
Proprietary/Trade name: SNM FirmGrip™ Peripherally Inserted Catheter Device

Classification name: SNM FirmGrip™ has been classified as **Class II** device under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	FOZ	880.5200	General Hospital

Predicate Device:

Modified SNM FirmGrip™ - Peripherally Inserted Catheter Device is substantially equivalent to the original FirmGrip™ Peripherally Inserted Catheter Device, cleared under 510(k) number K080793.

Device description:

Flexicath's *SNM FirmGrip™* is actually the same device cleared under K080793 except for the addition of **Safety Needle Mechanism (SNM)** to the Cleared *Needle Unit Assembly*.

The **Safety Needle Mechanism** is a unique feature enables needle retraction into a tubular housing once it is taken out from the patient vein. Once the needle is withdrawn from the vein, the safety mechanism is activated by a simple press on the safety mechanism Activation Button (Locking Clip).

The SNM has a male connector which is used to be inserted into the *FirmGrip™ PeelGuard's* female connector when being integrated with the FirmGrip™ Catheter and Catheter Sleeve at the Catheter insertion stage.

The compressed spring is being restrained by a Locking clip which used to hold it in place until safety mechanism is activated. Once the Locking clip button is pushed, the SNM is being activated and the needle is being retracted and fully covered. At this stage the FirmGrip™ Needle Unit Assembly and the SNM are ready to be disposed.

Intended use:

The SNM FirmGrip™ Peripherally Inserted Catheter Device is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling.

Technological characteristics and Substantial Equivalence:

The modified SNM FirmGrip™ - Peripherally Inserted Catheter is substantially equivalent the FirmGrip™ that was previously cleared under 510(k) number K080793.

Both new and predicate devices have the same indication for use, same basic shape, design and characteristics. The new device has the addition of the Safety Needle Mechanism which intends to protect both patient and medical staff from needlesticks. All changes that differs the modified device from the original (predicate) device were fully addressed and evaluated.

The modifications performed do not affecting the device's intended use and do not alter the device's fundamental scientific technology.

New device's verification and validation tests showed that it is as safe and as effective as the predicate device.

None clinical performance data:

Tests results are supporting all labeling claims and substantial equivalency. The modified device was tested with according to Flexicath's legally marketed device specification and applicable standards. All acceptance criteria were met.

Conclusions:

The evaluation of Flexicath's SNM FirmGrip - Peripherally Inserted Catheter Device non-clinical tests, demonstrates that the device is as safe and as effective as the predicate device. Therefore, we believe it is substantially equivalent to Flexicath's legally marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 25 2009

Ms. Tali Hazan
Regulatory Affairs Advisor
Flexicath, Limited
120 Yigal Alon Street, Suite 107
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ISRAEL

Re: K092629
Trade/Device Name: SNM FirmGrip™ - Peripherally Inserted Catheter Device
SNM - Safety Needle Mechanism
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: August 24, 2009
Received: August 27, 2009

Dear Ms Hazan:

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.

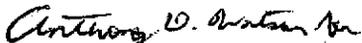
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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" (21 CFR 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,


Susan Ruiner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Section 4: Indication For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: SNM FirmGrip™ - Peripherally Inserted Catheter Device
**SNM – Safety Needle Mechanism*

Indications for use: The SNM FirmGrip™ - Peripherally Inserted Catheter Device is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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(Posted November 13, 2003)

510(k) Number: K092629