FLEXICATH Ltd.

MAY - 7 2007

SECTION 5 - 510(K) SUMMARY

FIRMGRIP™ PERIPHERALLY INSERTED CATHETER DEVICE

510(k) Number K063363

Applicant's Name:

Company name: **FlexiCath Ltd.**
Address: 120 Yigal Alon St.
California Building, Suite 107
Tel Aviv, 67443
ISRAEL
Tel.: +972 (4) 8500076
Fax: +972 (4) 8500684
E-mail: mail@flexicath.com

Contact Person:

Contact Name: Ahava Stein
Company: A. Stein – Regulatory Affairs Consulting
Address: 20 Hata'as St. (P.O.B. 124)
Kfar Saba 44425
ISRAEL
Tel.: +972 (9) 7670002
Fax.: +972 (9) 7668534
E-mail: asteinra@netvision.net.il

Date Prepared:

Date: November 1, 2006

Name of the device:

Peripherally Inserted Catheter Device

Trade or proprietary name, if applicable:

FirmGrip™ Peripherally Inserted Catheter Device

K083636 (2 of 5)

Common or usual name:

Peripherally Inserted Catheter

Establishment Registration No.:

Establishment registration form (Form FDA 2891) has been submitted but no registration number has been assigned yet.

Classification Name:

Therapeutic, long-term (greater than 30 days), intravascular catheter (21 CFR 880.5970, Product Code LJS)

Classification:

FDA has classified Therapeutic, long-term (greater than 30 days), intravascular catheters as Class II devices (product code LJS), which are reviewed by the General Hospital Devices Panel.

Predicate Device:

The FirmGrip™ Peripherally Inserted Catheter device is substantially equivalent to a combination of the MedComp Z-Cath Catheter devices (manufactured by MedComp Corp. and the subject of 510(k) document no. K003682), the Seldiflex Central Venous Catheter (manufactured by Plastimed Laboratoire Pharmaceutique and the subject of 510(k) document no. K992424) and the Over the Needle (OTN) Splitable Catheter Introducer (manufactured by Teleflex Inc. and the subject of 510(k) document no. K920908), in terms of intended use, indications for use, technological characteristics, performance and user interface. The predicate devices are also Class II medical device.

Device Description:

The FirmGrip™ peripherally inserted catheter includes a standard catheter encapsulated in a specially designed protective sleeve. The protective sleeve enables manipulation, handling, and insertion of the catheter .

The catheter component is a standard, legally marketed catheter. The FirmGrip™ peripherally inserted catheter contains color coded hubs, one cm markings for easier length determination, and is fully radio-opaque. The catheter is incorporated into the FirmGrip™ sterile protective sleeve. A specially designed adapter, called the PeelGuard, and a PeelAway Needle Introducer are supplied with the FirmGrip™ device.

The FirmGrip™ protective sleeve comprises a long sheath with a special handgrip and a friction unit at the tip. The handgrip portion is located near the tip of the protective sleeve. The special handgrip is shaped like an accordion and moves back automatically in an accordion-like motion to facilitate the catheter insertion. The catheter is advanced slowly by grasping the catheter through the handgrip portion of the FirmGrip™ protective sleeve and pushing it forward. Pressure is released to allow the accordion-like motion of the protective sleeve to return the handgrip portion to its original position. The catheter is continuously advanced as described above until the catheter is completely in place.

The long sheath portion of the protective sleeve contains the catheter and is designed to accommodate the length of a midline catheter. The tip of the catheter is located within the tip of the protective sleeve and the remainder of the catheter lies within the long sheath portion. The tip of the protective sleeve contains butterfly wings for ease of use, holding and securing the catheter in place. The tip of the protective sleeve is closed with a luer cap until use. When ready for use, the luer cap is removed and the specially designed adapter, called the PeelGuard is attached to the tip of the protective sleeve.

The tip of the protective sleeve connects to the peel-away needle introducer via the PeelGuard adapter. Upon placement of the catheter within the vein, the remainder of the catheter may be removed from the protective sleeve by pulling back on the hand grip of the protective sleeve.

The final device is packaged in a blister pack and sterilized by EtO Sterilization

Intended Use / Indication for Use:

The 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.

Comparison of Technological Characteristics with the predicate device:

The catheter component of the FirmGrip™ Peripherally Inserted Catheter device is similar to the Z-Cath Catheter devices (MedComp Corp., USA) both in intended use and in technological characteristics. Both devices are peripherally inserted catheter devices intended for use for obtaining venous access. The FirmGrip™ catheter is a shortened version of the MedComp catheter. The catheters are manufactured from the exact same materials and contain the exact same components. Both the catheters meet the requirements of the biocompatibility standard (ISO 10993) and have been testing in accordance with the ISO 10555 standard for sterile, single-use intravascular catheters. The only difference between the catheters is that the MedComp catheter is 60 cm long and is intended for central line catheterization procedures, whereas the FirmGrip™ catheter is 16 cm long and is intended for use as a midline catheter for peripheral venous access.

The FirmGrip™ sterile sleeve is similar to the Seldiflex Central Venous Catheter (Plastimed Laboratoire Pharmaceutique, France) both in intended use and in technological characteristics. Both devices are peripherally inserted catheter devices intended for use for obtaining venous access. Both devices are comprised of a catheter component supplied in a protective sheath for the purpose of maintaining a sterile environment. The difference between the devices is that the Plastimed protective sheath is made from Silver Dacron and the FirmGrip™ protective sheath is made from silicone.

The peel-away needle introducer supplied with the device is substantially equivalent to the Over the Needle (OTN) Splitable Catheter Intoducer (Teleflex Inc.) both in intended use and in technological characteristics. Both devices are catheter introducer devices intended for use for percutaneous insertions of small diameter catheters such as PICC, Midline catheters. The FirmGrip™ peel-away needle introducer is manufactured from the exact same materials and contains the exact same components as the Teleflex device.

Non-Clinical Performance Data and Performance Standards

In-vitro testing was performed on the FirmGrip™ Peripherally Inserted Catheter to assure reliable design and performance in accordance with the ISO 10555 standard.

Biocompatibility testing on the FirmGrip™ Peripherally Inserted Catheter demonstrates that the materials used meet the requirements of ISO 10993 for a permanent contact device. Other components of the device are manufactured from materials that are used in other legally marketed medical devices for a similar purpose.

A final device performance test was conducted on the FirmGrip™ Peripherally Inserted Catheter device to verify the proper advancement of the catheter through the sterile sleeve using the handgrip portion of the sleeve intended for this purpose.

Conclusions Drawn from Non-Clinical Tests:

The non-clinical tests demonstrated that the FirmGrip™ Peripherally Inserted Catheter device meets its design and performance specifications. Furthermore, the final device performance test showed that the FirmGrip™ Peripherally Inserted Catheter device is easy to use and performs as intended.

Substantial Equivalence:

The FirmGrip™ Peripherally Inserted Catheter device has the same intended use as the predicate devices. The FirmGrip™ Peripherally Inserted Catheter has the same technological characteristics, (i.e., same materials, design and principle of operation) as the predicate catheter device (MedComp, USA). The FirmGrip™ Peripherally Inserted Catheter device includes a sterile protective sheath that is similar to another predicate catheter device (Plastimed, France). The differences in the new device do not raise new issues of safety or effectiveness based on the non-clinical testing and relevant predicate devices.

Therefore, we believe that the FirmGripTM Peripherally Inserted Catheter device is substantially equivalent to the predicate devices cited above and therefore may be cleared for marketing in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FlexiCath Limited
C/O Ms. Ahava Stein
Regulatory Affairs Manager
A. Stein Regulatory Affairs Consulting
Beit Hapa'amon Box 124
20 Hata'as Street
44425 Kfar Saba
ISRAEL

MAY - 7 2007

Re: K063363
Trade/Device Name: FirmGrip™ Peripherally Inserted Catheter Device
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 24, 2007
Received: April 30, 2007

Dear Ms. Stein:

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.

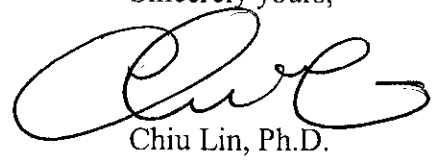
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Section 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: FirmGrip™ Peripherally Inserted Catheter Device

Indications for use: The 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.

Prescription Use __√__ OR Over-The-Counter Use___
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number K963363