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Pitango Medical Ltd.

510(k) Summary:

ComCaSet-P Safety IV Catheter

AUG 16 2007

Company Name:

Pitango Medical Ltd. Ltd.

Contact Person: Ben Levin
Managing Director
Telephone: +972-3-613-0480
Fax: +972-3-613-0481
E-mail: belevin@pitangomedical.com

Authorized US Agent:
George J. Hattub, RAC & CQE
Senior Staff Consultant
MedicSense Inc.
291 Hillside Avenue
Somerset, Massachusetts 02726

Phone: (508) 479-6116
Fax: (508) 677-1418
E-Mail: george@medicsense.com

Date prepared: December 27, 2006

Trade Name: ComCaSet-P Safety IV Catheter.

Classification name: Intravascular catheter

Class: II

Panel identification: General Hospital Devices

Product code: FOZ

Regulation number: 880.5200

Predicate Device: ComCaSet Safety IV Catheter, Pitango Medical Ltd, Ramat Gan, Israel, cleared under 510(k) no. **062108**.

Pitango Medical Ltd.

Device description:

The ComCaSet-P Safety IV Catheter consists of several parts common to most IV catheters: stainless steel needle, Teflon catheter tube with hub and the catheter body. In addition, the ComCaSet-P Safety IV Catheter has a safety locking mechanism which enables the needle and the flash chamber to retract into a safety barrel

Disconnecting the needle assembly and catheter hub from the catheter releases the latex-free elastic rubber band and allows the needle and flash chamber to retract quickly into the safety barrel.

The product is available in seven gauges identified also by specific colors as follows:

Size	**Color**	**Catheter**		**Catheter Length(mm)**	**Water Flow Rate (ml./min.)**
		I.D. mm	O.D. mm		
14G	Orange	1.7	2.1	45	270
16G	Grey	1.3	1.7	45	180
17G	White	1.1	1.5	45	125
18G	Green	0.9	1.3	45	80
20G	Pink	0.8	1.1	32	54
22G	Blue	0.6	0.9	25	33
24G	Yellow	0.5	0.7	19	20

Indications for Use:

The ComCaSet-P Safety IV Catheter is indicated to sample blood, monitor blood pressure, or administer fluids intravenously. The ComCaSet-P Safety IV Catheter may be used for any patient population with consideration given to adequacy of the vascular anatomy appropriateness for the solution being administered and duration of the therapy. The ComCaSet-P Safety IV Catheter provides a shielding mechanism intended to reduce the incidence of accidental needle sticks. When the catheter hub and needle assembly components are withdrawn, the shielding mechanism is activated and the needle retracts into the shielding tube.

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Pitango Medical Ltd.

Substantial Equivalence:

The ComCaSet Safety-P IV Catheter has the same intended use and the same principle of operation as the **ComCaSet Safety IV Catheter** cleared under 510(k) no. K**062108**. The main technological difference between ComCaSet-P Safety IV Catheter and the predicate devices is the release element of the needle retraction element, which at the ComCaSet-P Safety IV Catheter is activated by the separation of the catheter hub and needle assembly from the catheter.

Conclusion:

The evaluation of the ComCaSet-P Safety IV Catheter does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ben Levin
Managing Director
Pitango Medical Limited
3A Jabotinski Street, 28th Floor
Diamond House-Doron Levy
Ramat Gan, Israel 52520

AUG 16 2007

Re: K070020
Trade/Device Name: ComCaSet-P Safety IV Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 31, 2007
Received: August 6, 2007

Dear Mr. Levin:

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.

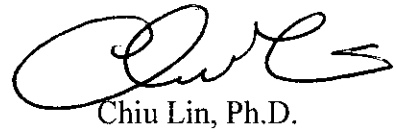
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

K070020

Indications for Use

510(k) Number (if known): K070020

Device Name: ComCaSet-P Safety IV Catheter

Indications for Use:

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Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K070020