

KP62148 (P.10A3)

Pitango Medical Ltd.

510(k) Summary:

AUG - 8 2006

ComCaSet Safety IV Catheter

Company Name:

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Senior Staff Consultant

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E-Mail: george@medicsense.com

Date prepared: May 25, 2006

Trade Name: ComCaSet Safety IV Catheter.

Classification name: Intravascular catheter

Class: II

Panel identification: General Hospital Devices

Product code: FOZ

Regulation number: 880.5200

Predicate Devices: Insyte™ Autoguard™ Shielded IV Catheter form
Becton-Dickinson Infusion Therapy Systems Inc in Sandy, Utah, cleared under
510(k) no. K984059

Pitango Medical Ltd.

Device description:

The ComCaSet 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 Safety IV Catheter has a safety locking mechanism which, when activated, enables the needle and the flash chamber to retract into a safety barrel

The activation element holds the needle assembly in the forward position until the user activates the device. Pulling the activator releases the latex-free elastic rubber band and allows the needle and flash chamber to retract quickly into the safety barrel. In this way user maintains control of the process by determining when to activate the safety mechanism.

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 Safety IV Catheter is indicated to sample blood, monitor blood pressure, or administer fluids intravenously. The ComCaSet 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 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 When the catheter hub and needle assembly components are withdrawn, the user activates the shielding mechanism and the needle retracts into the shielding tube.

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Pitango Medical Ltd.

Substantial Equivalence:

The ComCaSet Safety IV Catheter has the same intended use and the same principle of operation as the **Insyte™ Autoguard™ Shielded IV Catheter** from Becton-Dickinson Infusion Therapy Systems Inc in Sandy, Utah, cleared under 510(k) no. **K984059**. The main technological difference between ComCaSet Safety IV Catheter and the predicate devices is the release element of the needle retraction element, which at the ComCaSet Safety IV Catheter consists of a latex-free elastic rubber band and at the predicate device consists of a spring.

Conclusion:

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2006

Pitango Medical Limited
C/O Ms. Patricia L. Murphy
Responsible Third Party Official
Kema Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K062108
Trade/Device Name: ComCaSet Safety IV Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 18, 2006
Received: July 24, 2006

Dear Ms. Murphy:

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.

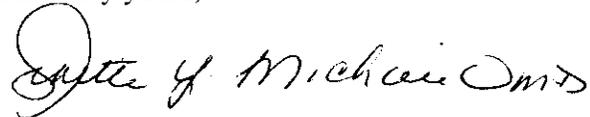
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K062198

Device Name: ComCaSet Safety IV Catheter

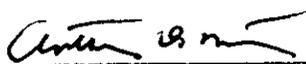
Indications for Use:

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



(Signature)
Department of Anesthesiology, General Hospital,
Quality Control, Dental Devices

Device Number: K062198
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