K060109

MAY - 5 2006

EXHIBIT 2
510(k) Summary

VitalCare Group, Inc.
8935 N.W. 27th Street
Miami, Florida 33172 USA
Telephone 305-620-4007
Fax 305-620-5220
Contact: Ramzi Abulhaj, President
November 3, 2005

1) Identification of the Device:
Proprietary-Trade Name: OMI Retractable Safety Syringe
Classification Name: Piston Syringe
Common/Usual Name: Safety Syringe

2) Equivalent legally marketed device: SEZ Safety Syringe, K031163

3) Indications for Use (intended use) . This device is a safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries. EO sterilized, non-pyrogenic, and latex free.

4) Description of the Device: The OMI Retractable Safety Syringe works like this:
STEP 1 After cap removal, fluid draw-up and aspiration is unchanged from conventional syringes.
STEP 2 As the plunger rod is depressed and the plunger stopper makes contact with the needle hub, the elastic membrane conforms to the conical shape of the needle hub. The plunger stopper membrane stretches until the plunger rod is fully depressed and maximum fluid is expelled from the syringe.
STEP 3 At the point of full plunger rod depression, the application of the injection force overcomes the strength of the web joining the inner and outer portions of the needle hub. As this web fractures and the outer portion of the needle hub moves forward, the plunger stopper membrane is simultaneously pierced by the conical end of the hub, releasing the inner portion of the hub carrying the needle to be retracted into the hollow stem of the plunger rod by the coiled spring. The activation force is controlled. The extra pressure required at the end of the injection stroke to retract the needle is minimal. The entire procedure designed for singlehanded use, with no change to common habits.
STEP 4 The fracturing of the needle hub and the piercing of the plunger stopper allow the needle to be forced into the plunger rod by the coiled spring. The speed of this retraction and the minimal dead space avoids blood or fluid spatter. Retraction is accompanied by an audible "click" and the highly visible separation of the needle hub.

The syringe is EO sterilized, non-pyrogenic, and latex free.

5) Safety and Effectiveness, comparison to predicate device:

Device Name	SEZ safety syringe [K031163]	OMI Retractable Safety Syringe
Intended Use	This device is a Safety hypodermic syringe for Intramuscular and Subcutaneous injection. This device aids in prevention of needlestick injuries. EO sterilized, non-pyrogenic, and latex free.	Identical
Principle operation	Activation of safety feature consists of two steps : 1) Disassemble needle assembly from the barrel by turning the plunger 2) Retract needle into barrel and confine it in the barrel by pushing the plunger forward before disposal.	Activation of safety feature consists of the following single step: After injecting the medicine, the plunger is pushed in just a bit harder causing the retraction mechanism to pull the needle permanently inside the barrel.
Volume (ml/cc)	3 and 5	1, 3, 5 and 10 ml sizes
Nozzle type	Female conical lock fitting with rotatable internally threaded neck	Needle and hub are integral to the syringe, not separable.
Barrel Marking	Scale: confirms to ISO7886-1:1993(E)	Identical
Reuse	Non-reusable	Identical
Biocompatibility	Conform to ISO 10993-1	Identical
Materials	1) Plastic parts : polypropylene (homo type)	Identical
	2) Gasket : thermoplastic rubber	Identical
	3) Packing film : Medipeel film	Identical
	4) Packing paper : Ethypel paper	Identical
Sterility	Sterilized by ethylene oxide gas SAL = 10^{-6}	Identical

6) Conclusion: In all material respects, the OMI Retractable Safety Syringe is substantially equivalent to the predicate device. The conclusion is based on biocompatibility testing, clinical testing, compliance with voluntary standards, and comparison to the predicate device. A clinical investigation was performed, and test for the comparison between OMI Retractable Safety Syringe and the legally marketed predicate device was performed in accordance with "Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA". The results of the investigation showed that the OMI Retractable Safety Syringe is clinically acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2006

VitalCare Group, Incorporated
C/O Mr. Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K060109
Trade/Device Name: OMI Retractable Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: January 11, 2006
Received: February 8, 2006

Dear Mr. Kamm:

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.

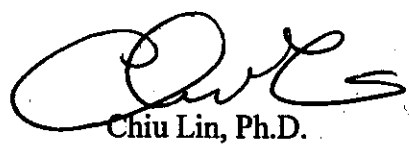
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K060109

Device Name: OMI Retractable Safety Syringe

Indications For Use:

This device is a safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries. EO sterilized, non-pyrogenic, and latex free.

Prescription Use _X_ 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K060109