K043419 (1/2)

APR 15 2005

510(K) Summary

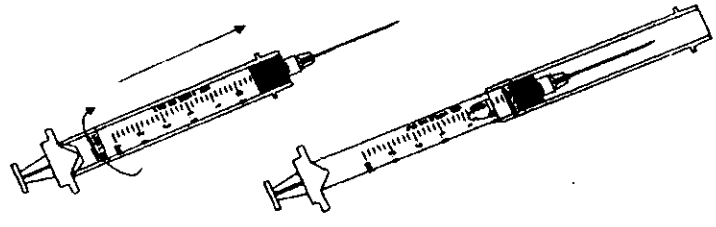
Medexel Medical Manufacturing Co., Ltd.
536-65 Kumkwang-Ri KumKwang-Myun,
Ansung-Si, Kyunggi-Do, 456 - 862 Korea
Tel : 82-31-677-8004~6
Fax : 82-31-677-8007
Contact: J. M. Shim, Managing Director
March 1, 2005

1) Identification of the Device:
Proprietary-Trade Name: p&p 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.

4) Description of the Device: The p&p Safety Syringe consists of a calibrated hollow barrel (which can contain the medication) and the distal end of the barrel has Luer Lock Tip. The needle can be changed depending on the required gauge, since the syringe is compatible with general needles. The Safety Cap can be moved back and forth as safety feature. The safety cap has a printing mark "LOCK LINE". The adaptor is colored with medical grade blue pigment . The plunger and gasket are the same shape as the conventional syringes. When user gives the intramuscular/subcutaneous injection, he/she pushes the knob of the plunger to the end. After completing the intramuscular/ subcutaneous injection, the user turns the safety cap to the left side, and then pushes it forward until the marking ("LOCK LINE") on the safety cap touches the bottom line of the blue adaptor in order to lock the safety cap and the adaptor. The blue color of the adaptor allows the user to distinguish the locking position clearly and easily. Then the safety cap can no longer be moved back and forth, thus preventing needlestick injury. Then the syringe can be disposed in the appropriate sharps container. This is a simple and elegant design which is highly reliable.



5) Safety and Effectiveness, comparison to predicate device:

Device Name	SEZ safety syringe [K031163]	p&p Safety Syringe
Intended Use	This device is a Safety hypodermic syringe for Intramuscular and Subcutaneous injection. This device aids in prevention of needlestick injuries.	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 steps : 1) While holding the safety sheath. 2) Turn the flange of the barrel to the right. And pull it back until "LOCK LINE" touches the bottom of the blue adaptor. Dispose the syringe into the sharps container.
Volume (ml/cc)	3	3
Nozzle type	Female conical lock fitting with rotatable internally threaded neck	Male conical lock fitting (Luer Lock Tip) with rotatable internally threaded neck
Barrel Marking	Scale: conforms 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	Identical
	SAL = 10^{-6}	

6) Conclusion: In all material respects, the p&p 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 p&p 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 p&p Safety Syringe is clinically acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Medexel Medical Manufacturing Company Limited
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
PO Box 7007
Deerfield, Illinois 60015

Re: K043419
Trade/Device Name: p&p Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 4, 2005
Received: March 25, 2005

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.

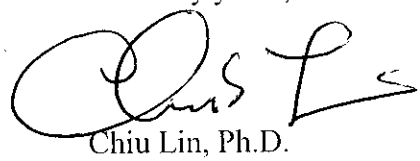
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K043419

Device Name: p&p 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.

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

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