510(k) Summary

FEB 13 2009

1.) Submitted by: Revolutions Medical Corporation Inc.
2073 Shell Ring Circle
Mount Pleasant, SC 29466
Registration: 10027335

2.) Contact: Revolutions Medical Corporation Inc.
2073 Shell Ring Circle
Mount Pleasant, SC 29466
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617-899-3449
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DROTHK@AOL.COM

3.) Device Name: ReVac Auto Retractable Safety Syringe

4.) Classification Name: Piston Syringe (with permanently attached needle)

5.) Device Class: Class II, 21 CFR 880.5860

Panel: 80

Product Code: FMF, MEG

6.) Predicate Devices:

Futura Safety Syringe K000860

7.) Device Description:

The ReVac (Reverse Vacuum) Safety Syringe is a piston type hypodermic syringe with an automated needle retraction system. The device works like a typical syringe in that after removal of the cap, the user pulls back the syringe to feed liquid back into the barrel. Once the plunger is fully depressed, and the fluid inside is fully dispensed, a vacuum is created that is sufficient to force the retraction of the needle into the hollow chamber of the syringe. The needle is not visible and is fully inaccessible. The needle cannot be removed from the syringe without completely destroying the syringe.

The ReVac (Reverse Vacuum) Safety Syringe is a piston type hypodermic syringe with an automated needle retraction system. It is sterile, non-toxic, non-pyrogenic, retractable syringe designed to provide a safe reliable method for intramuscular and subcutaneous injection of drugs and or fluids while helping to provide protection from accidental needle sticks.

8.) Device Intended Use:

The Reverse Vacuum (RevVac) Safety Syringe is a sterile, single use, disposable, auto-retracting safety piston syringe which is intended for injection of fluid into the body, while reducing the risk of sharps injury and the potential for syringe reuse. The device is intended for use for subcutaneous and intramuscular use.

9.) Substantial Equivalence Comparison

A. Revolutions Medical Corporation makes the claim of substantial equivalence of the ReVac Safety Syringe to the Futura Safety Syringe K000860 based on similarities in intended use, design, and system performance. Both devices are indicated for injecting fluids into the body with a permanently fixed, single lumen hypodermic needle, while helping to reduce the risk of needle sticks. Both products are piston syringes, provided sterile, single-use and disposable. Lastly both syringes retract the contaminated hypodermic needle safely inside syringe immediately after the completion of the patient injection.

10.) Brief Description of Testing

The testing provided in the premarket notification includes biocompatibility and standard conformity. Side by Side equivalence information with the Futura Safety Syringe is provided to show that the two products are equivalent in performance. The testing supports the claimed indications for use.
The ReVac safety syringe 3cc/ml was tested to the internationally recognized standards listing in Table 1.

Standard ID	Title
ISO 7886-1: 1993	*Sterile Hypodermic syringe for Single Use*
ISO 7886-3:2005	*Sterile Hypodermic syringe for Single Use –Auto disable Syringes for Fixed Dose Immunization*
ISO7864: 1993	*Sterile Hypodermic Needle for Single Use-Syringes for Manual Use*
ISO 10993-1:1997	*Biological Evaluation of Medical Devices —Evaluation and testing*

Table 1

In addition, the contents of this premarket notification are provided with the consideration of the FDA's "Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes; FDA April 1993" and "*Medical Devices with Sharps Injury Prevention Features* - Guidance for Industry and FDA Staff."

11) Conclusion
Revolutions Medical believes that the ReVac Auto Retractable Safety Syringe is substantially equivalent to the predicate device Futura Safety Syringe based on intended usage and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2009

Son Medical
C/o Mr. Richard Theriault
Acting Vice President Engineering/Manufacturing
Revolutions Medical Corporation
2073 Shell Ring Circle
Mount Pleasant, South Carolina 29466

Re: K083193
Trade/Device Name: ReVac Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF
Dated: January 16, 2009
Received: January 22, 2009

Dear Mr. Theriault:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting 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 Form

510(k) Number (if known): K083193

Device Name: ReVac Safety Syringe

Indications for Use:

The Reverse Vaccuum (RevVac) Safety Syringe, is a sterile, single use, disposable, auto-retracting safety piston syringe which is intended for injection of fluid into the body, while reducing the risk of sharps injury and the potential for syringe reuse. The device is intended for use for subcutaneous and intramuscular use.

Prescription Use __X__ OR Over-the-Counter Use ___ 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083193