K051045

AUG 2 - 2005

SIMPLECHOICE
A SpectRx, Inc. Company
CORPORATE OFFICE
4955 Avalon Ridge Parkway * Suite 300
Norcross, GA 30071
Telephone: (770) 242-8723 Fax: (770) 242-8639

510(k) Summary

Date Submitted: July 14, 2005

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, a 510(k) Summary follows for a Device Modification:

Submitter: SpectRx Inc (d/b/a SimpleChoice), 4955 Avalon Ridge Parkway, Suite 300, Norcross, GA 30071

Contact: William M Vondersmith (770) 242-8723 ext 282

Name of Device: SimpleChoice *reservoir Pro* Reference Number RP-30

Modified Device: Sterling Medivations Simplicity Infusion Reservoir 510(k) K013767, Marketed as SimpleChoice *reservoir* Reference Number R-30

Description of Device: The SimpleChoice *reservoir Pro* (3.0mL), Reference Number RP-30, is a single use reservoir system used to deliver medications subcutaneously. The user fills the reservoir via a standard hypodermic needle provided with the device. The 3.0 ml *reservoir Pro* then attaches to an SimpleChoice infusion set having a female luer lock with a retainer feature, and is placed in an external infusion pump. If the reservoir will be used with a Paradigm pump the plunger rod is detached and the reservoir is secured with the retainer feature.

The modifications which are the subjects of this premarket notification have no untoward effect on the safety and effectiveness of the device.

Intended Use of the Device: The intended use of the SimpleChoice *reservoir Pro* is to provide a means to infuse medicine, including insulin, from an external infusion pump. The reservoir is not intended for use with blood or blood products.

Comparison of the Technology Features of the Modified Device: The SimpleChoice *reservoir Pro* modified device design of the SimpleChoice *reservoir*, a legally marketed device. They differ slightly in filling mechanism, i.e., ability to detach the plunger rod and retain in the Medtronic MiniMed Paradigm pumps. The new device is as safe, as effective, and performs the same as the original device, the SimpleChoice *reservoir*.

Summary and Conclusion of Non-clinical and Clinical Tests:
The intended use of the SimpleChoice *reservoir Pro* is identical to that of the SimpleChoice *reservoir*, the original device. There is no difference in technological characteristics and there are no new significant issues of safety or effectiveness. The tests performed show such equivalence.

William M. Vondersmith
Quality Assurance/Regulatory Affairs Manager
SpectRx Inc /SimpleChoice

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 - 2005

Spectrx, Incorporated
c/o Mr. William M. Vondersmith
4955 Avalon Ridge Parkway, Suite 300
Norcross, Georgia 30071

Re: K051045
Trade/Device Name: SimpleChoice 3.0 ML Reservoir Pro Reference Number RP-30
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN
Dated: July 14, 2005
Received: July 15, 2005

Dear Mr. Vondersmith:

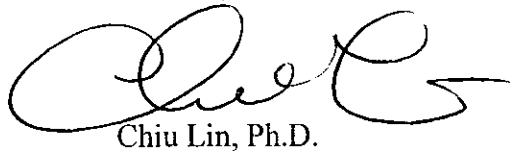
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): K051045

Device Name: SimpleChoice *reservoir Pro*

Indications For Use:

The intended use of the SimpleChoice *reservoir Pro* is to provide a means to infuse medicine, including insulin, from an external infusion pump. The reservoir is not intended for use with blood or blood products.

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: K051045