K092016

6.0 510(k) Summary

Date of Submission: June 12, 2009

Submitted by:

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Director QARA
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Stat Medical Devices, Inc.
2056 NE 153rd Street
North Miami Beach, Florida 33162

OCT - 2 2009

Name of Device: Stat Medical Pen Needle
Common or Usual Name: Sterile disposable hypodermic needle
Proprietary Name: Super-Fine Pen Needle
Classification Name: Hypodermic single lumen needle
Classification Product Code: FMI
Class: II

Intended use:
The Stat Medical Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin. This is the **same intended use** as previously cleared for the Stat Medical Pen Needle, K042917.

Description of Device:
The Stat Medical Pen needle consists of 4 parts, the needle, the needle hub, the needle protector and the outer cover. The cannula is manufactured from 304 stainless steel. The cannula is produced into three sizes for the device (the 29g 12.7 mm (1/2 in), 31g 5mm (3/16 in) and the 31g 8mm (5/16 in). The cannula length and inner diameter are a constant for these three sizes, which differ in the outer diameter of the cannula.

The hub is molded from medical grade polypropylene, and medical grade silicon. The needle is glued into place in the hub and is coated with a medical grade silicon/lube. The silicone oil/lube is non-toxic, pyrogen free, and free from contamination. After assembly, the hub and needle assembly are tested, packaged, and sterilized.

The Stat Pen Needle is provided sterile via EO sterilization and is for Single Use only.

The modification to the original filing is the correction of where the silicon coating is applied to the device, and a change in the product labeling to include the identification of the silicon coating. Product labeling may be found in section 9 of this submission.

Substantial Equivalence:
The modified Stat Medical Pen Needles have the same following similarities to devices that previously received 510(k) clearance:

- same indication for use
- same operating principle

- incorporation of same materials
- same sterilization and packaging materials and processes
- same basic design

In summary, the Stat Medical Super Fine Pen Needle described in this submission are, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Mary L. Jean
Director of Quality Assurance/Regulatory Affairs
Stat Medical Devices, Incorporated
2056 North East 153rd Street
North Miami Beach, Florida 33162

OCT - 2 2009

Re: K092016
Trade/Device Name: Super-Fine Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 3, 2009
Received: September 4, 2009

Dear Ms. Jean:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092016

Indications for Use

510(k) Number (if known): K092016

Device Name: Super-Fine Pen Needles

Indications for Use:

The Stat Medical Super-Fine Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

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

510(k) Number: K092016