K023722

SEP - 2 2003

510(k) Summary

Submitted by: Daniel J. Manelli
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2000 M Street NW (Suite 700)
Washington, DC 20036

Phone: 202-261-1000

On behalf of Spintech, Inc.
220 South Orange Avenue
Livingston, NJ 07039

510(k) Submission: SafetyWand™ disposable handpiece for CompuDent™ anesthetic delivery system

Date:August 13, 2003

Description: The SafetyWand™ disposable handpiece is a safety engineered syringe component designed for use with the CompuDent™ computer controlled injection system (K992819). The CompuDent® device utilizes hypodermic needles and standard 1.8mm pre-filled carpules manufactured by various third parties. The anesthetic agent reaches the needle by means of a length of flexible vinyl tubing. The hanbdpiece is made of rigid PVC. The anesthetic cartridge holder, the tubing and the handpiece are sold in a sterile condition as a disposable assembly for one-time use. The materials, principal of operation and intended use are the same as other marketed piston and cartridge syringes. The device provides audible status indicators, including optional voice announcement of injection rate, and volume of anesthetic dispensed.

The SafetyWand™ handpiece incorporates a protective barrel inside of which a movable needle hub assembly can be extended and locked in place for use in performing injections. When not in use, or for disposal, the needle can be retracted within the barrel to aid in the prevention of needlesticks. The SafetyWand™ is substantially equivalent to the company's Wand® handpiece (K992819) and to the IntegriTech Safety Injection System (K962999).

Indications for use:

To inject local anesthetic agents subcutaneously or intramuscularly for dental applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Spintech, Incorporated
Mr. Daniel J. Manelli
Attorney
2000 M Street NW (Suite 700)
Washington, DC 20036

Re: K023722
Trade/Device Name: SafetyWand™ Disposable Handpiece
Regulation Number: 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: June 20, 2003
Received: June 20, 2003

Dear Mr. Manelli:

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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023722

Device Name: SafetyWand™ disposable handpiece

Indications for Use:

The SafetyWand™ is intended to inject local anesthetic agents subcutaneously or intramuscularly for dental applications. It is a sterile single use handpiece assembly for use with the Milestone Compudent™ computer controlled injection system. The SafetyWand™ incorporates safety engineering sharps protection features to aid in the prevention of needlesticks.

Susan Runyan

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

510(k) Number: K023722

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)