K992819

Exhibit B

MAY 11 2000

510(k) Summary

Submitted by: Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street NW (Suite 700)
Washington, DC 20036

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

510(k) Submission: The Wand Plus™ Syringe
Date: December 10th, 1999

Description: The Wand Plus™ is a computer controlled syringe consisting of a stationary motor housing which includes a metal piston whose speed of advance is regulated by a foot switch thus controlling the flow rate of anesthetic being injected. The 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 handpiece is made of rigid PVC. The holster containing the anesthetic carpule, 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. It is substantially equivalent to the company's currently marketed Wand™ computer controlled syringe.

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

MAY 11 2000

Spintech, Incorporated
C/O Mr. Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M street, N.W., Suite 700
Washington, DC 20036

Re: K992819
Trade Name: Wand Plus
Regulatory Class: II
Product Code: EJI
Dated: April 4, 2000
Received: April 4, 2000

Dear Mr. Manelli

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992819

Exhibit A

510(k) Number (if known): K992819

Device Name: The Wand Plus™ Computer Controlled Anesthetic Delivery System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992819

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

(Optional Format 1-2-96)