K061904

510(k) Summary

AUG - 8 2006

Submitted by: Daniel J. Manelli
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Ave., NW (Suite 440)
Washington, DC 20015

Telephone: 202-885-5548

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

510(k) Submission: CompuDent STA™ Syringe
Date: July 5, 2006

Description: The CompuDent STA™ Syringe 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 and visible status indicators of injection rate, amount of anesthetic remaining in the carpule, and pressure at the tip of the needle. It is substantially equivalent to the company's currently marketed CompuDent™ 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

AUG - 8 2006

Milestone Scientific, Incorporated
C/O Mr. Daniel J. Manelli
Attorney
Manelli & Fisher, P.L.L.C
5335 Wisconsin Avenue NW, Suite 440
Washington, D.C. 20015

Re: K061904
Trade/Device Name: CompuDent STA™
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: July 5, 2006
Received: July 5, 2006

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.

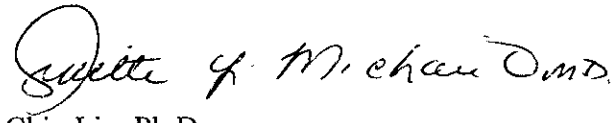
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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 (240) 276-3150 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

Exhibit 4

K061904

510(k) Number (if known): K061904

Device Name:

CompuDent STA™

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

...ction Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061904

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.1091)

(Optional format 1- 2 - 96)