JUN 2 4 2004

K041280

VIII. Special 510-(k) Summary

The summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

Submitter Information:

Regulatory/Clinical Consultants, Inc.
200 NE Mulberry, Suite 200
Lees Summit, MO 64086

Contact Person:
Jim Stanley

Phone:
816-347-9224

Date Prepared: May 11, 2004

Device Information:

Proprietary Name: Human Subcutaneous Injector system

Common Name: Needle-free fluid injection system

Classification Name: Nonelectrically powered fluid injector

Predicate Devices:

K013256	Felton International's Bi-3M
Preamendment	Ped-O-Jet

Device Description: The Human Subcutaneous Injector system consists of a hand-held injector unit to which a multiple-dose vial of vaccine or medication can be attached. The unit is spring-powered and is connected to its hydraulic fluid power source, which is operated by a foot pump.

Intended Use: The needle-free fluid injector system is indicated for the delivery of vaccines or medications to the subcutaneous tissue by penetrating the skin under high pressure. The device is to be used by a health care professional only.

Summary: The performance characteristics are substantially equivalent to the Bi-3M according to test protocols conducted for dosage accuracy, penetration, force, focus, sound, and stream quality. Safety tests performed for contamination were successful.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2004

Felton International, Incorporated
C/O Mr. James E. Stanley
Associate Director of Quality Assurance
Regulatory/Clinical Consultants, Incorporated
200 NE Mulberry, Suite 200
Lee's Summit, Missouri 64086

Re: K041280
Trade/Device Name: Human Subcutaneous Injector System HSI 500
Regulation Number: 880.5430
Regulation Name: Nonelectrically Powdered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: June 10, 2004
Received: June 15, 2004

Dear Mr. Stanley:

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) 594-4618. 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,

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): K041280

Device Name: Human Subcutaneous Injector System HSI 500

Indications For Use: This needle-free fluid injector system is indicated for the delivery of vaccines or medications to the subcutaneous tissue by penetrating the skin under high pressure. This device is to be used by a health care professional only.

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)

for 6/24/04

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

510(k) Number: K041280