K092831

5. 510(k) Summary

See 510(k) Summary, below.

JAN 14 2010

1. Trade Name: **FEELject NEEDLES**
2. Common Name: Disposable Hypodermic Needle.
   Classification Name: Single Lumen Hypodermic Needle.
   Product Code: FMI
   Regulation: 880.5570
   Class of device : ClassII.

3. The legally marketed device to which we are claiming equivalence:
   BD Hypoint Needle (K070440)
4. Description of device:
   FEELject NEEDLES is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.
   . The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub)
   The needle cap covers intended to provide physical protection to the needle tube.

5. Intended Use: FEELject NEEDLES is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

6. Technological Characteristics: FEELject NEEDLES and the predicate device have identical technological characteristics and perform the same way as common hypodermic Needle.
   FEELject NEEDLES are offered in various gauge sizes and needle lengths
   They are sterilized by EtO gas
   FEELject NEEDLES are Non-toxic, Non-Pyrogenic disposable and intended for single use

7. Performance: Bench tests were performed.

   Bench testing included biocompatibility, sterility testing.

   The tests demonstrated that the device is as safe , as effective and performs in a substantially equivalent manner to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Feel Tech Corporation
C/O Mr. Peter Chun
President
300 Atwood
Pittsburgh, Pennsylvania 15213

JAN 14 2010

Re: K092831
Trade/Device Name: FEELject NEEDLES
Regulation Number: 21CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 18, 2009
Received: September 14, 2009

Dear Mr. Chun:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Anthony D. Watson, BS, MS, MBA
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): K09_____.

Device Name: **FEELject NEEDLES**

Indications For Use:
FEELject NEEDLES is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

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)

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

510(k) Number: K092831