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Miltex
Redefining Excellence

K083796

510(k) Summary

Submitted by: Miltex, Inc.
589 Davies Drive
York, PA 17402 USA

MAR - 9 2009

Contact Person: Jennifer Bosley, Regulatory Affairs Manager
Integra Medical Instrument Group
Miltex, Inc.
589 Davies Drive
York, PA 17402 USA
Phone: (717) 781-6392 Fax: (717) 840-3509

Date Prepared: December 19, 2008

Device Trade Name: Miltex® Dental Aspirating Syringes
Common/Usual Name: Aspirating Syringe
Proposed Classification: Syringe, Cartridge
21 CFR 872.6770 Class II, 76 EJI Dental

Device Description:

Miltex® Dental Aspirating Syringes include Standard Aspirating Syringes, Petite Aspirating Syringes, Self-Aspirating Syringe, Lightweight Self-Aspirating Syringe, Articulating Barrel Syringe and GripRite™ Standard and Petite Aspirating Syringes. All syringes are made of chrome-plated brass and stainless steel; Lightweight Self-Aspirating Syringe has aluminum handle. Syringes are reusable, sterilizable and packaged non-sterile.

Intended Use:

Miltex® Dental Aspirating Syringes are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.

Predicate Devices:

510(k) #	Device	Manufacturer
Preamendment	Cartridge Syringes	Union Broach Co. (now Miltex, Inc.)
Preamendment	Anesthetic Syringes	Henke-Sass, Wolf GmbH
K040671	Anthogyr Cartridge Syringes	Anthogyr
K851903	Astra Self-Aspirating Syringe	Astra Pharmaceutical Products, Inc.

Substantial Equivalence:

Miltex® Dental Aspirating Syringes are substantially equivalent to the legally marketed predicate devices with respect to intended use, fundamental technology, design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jennifer Bosley, MBA, RAC
Regulatory Affairs Manager
Intergra Medical Instrument Group
Miltex, Incorporated
589 Davies Drive
York, Pennsylvania 17402

MAR - 9 2009

Re: K083796
Trade/Device Name: Miltex® Dental Aspirating Syringes
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: March 2, 2009
Received: March 4, 2009

Dear Ms. Bosley:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1071

K083796

Indications For Use

510(k) Number (if known): _____

Device Name: Miltex® Dental Aspirating Syringes

Indications for Use:

Miltex® Dental Aspirating Syringes are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.

Prescription Use ✓ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 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: K083796