510(k) Summary

DEC 11 2009

Submitter: Arnold Tuber Industries DBA Sci-Dent, Inc.
Address: 97 Main Street, Hamburg, NY 14075
Phone number: 716-648-3363
Fax number: 716-648-9296
Contact person: Michael Tuber
Date prepared: 08/27/2009
Trade name: Cartridge Dental Syringe
Common name: Cartridge Syringe
Classification name: Cartridge Syringe
Substantial equivalence claimed to:

1. Miltex 510(k) Number – K083796
2. Anthogyr 510(k) Number – K040671

Dental Aspirating Syringes/Self Aspirating Syringes include standard, petite and medium sizes. All syringes are made of stainless steel and have aluminum handles. Syringes are reusable, sterilizable and packaged non-sterile.

Intended use: Cartridge Syringes are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.

Summary of technological characteristics: Cartridge syringes are produced with various sized thumb rings to accommodate a large spectrum of practitioners. They also come in different colors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

DEC 11 2009

Mr. Michael Tuber
President
Arnold Tuber Industries
97 Main Street
Hamburg, New York 14075

Re: K092943
Trade/Device Name: Cartridge Syringe
Regulation Number: 21CFR 872.6770
Regulation Name: Cartridge System
Regulatory Class: II
Product Code: EJI
Dated: August 27, 2009
Received: September 24, 2009

Dear Mr. Tuber:

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 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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:

Device Name: Cartridge Syringe

Indications for Use: Cartridge 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_____
(Per 21 CFR 801 Subpart D) (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)

Robert Beez MS for Dr. Kevin Mahy (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092943