Advanced Technology and Capital, Inc.
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

November 16, 2017

Re: K171254
Trade/Device Name: LeEject 2 Dental Syringe and Needle System
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: Class II
Product Code: EJI, DZM
Dated: October 16, 2017
Received: October 17, 2017

Dear E.J. Smith:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171254

Device Name

The LeEject 2 Syringe and Needle System

Indications for Use *(Describe)*

"The LeEject 2 Syringe and Needle System is indicated to be used in conjunction with LeEject Needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K171254

510(k) Summary

SPONSOR

Company Name:	Advanced Technology and Capital, Inc
Company Address:	5 Sylvan Ave., Englewood Cliffs, New Jersey 07632
Telephone:	201.803.5202
Contact Person:	Alexander Lee, DDS
Summary Preparation Date:	November 15, 2017

DEVICE NAME

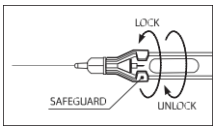
Trade Name:	The LeEject 2 Syringe and Needle System
Common/Usual Name:	Dental Aspirating Syringe
Classification Name:	Syringe, Cartridge
Regulation Number**:**	21 CFR 872.4730
Product Code:	EJI, DZM
Device Class:	Class 1

PREDICATE DEVICE

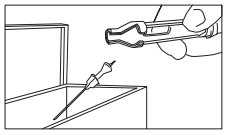
Legally Marketed Equivalent Device

Company	***Product***	***510(k) #***
Miltex, Inc.	Miltex Dental Aspirating Syringe	K083796
Biodent Co.	Denject Disposable Dental Needles	Exempt

DEVICE DESCRIPTION



The LeEject 2 Syringe and Needle System is a side-loading dental syringe with a plastic guard “Safeguard” to secure the needle. After inserting the LeEject Needle hub into the opening of the plastic Safeguard, rotating the “Safeguard” guard clockwise secures the dental needle.



The LeEject 2 Syringe and Needle System give the user the option of recapping the dental needle prior to disposal or unlocking the “Safeguard” and allowing the needle to fall into the sharps container without recapping.

The LeEject 2 Syringe’s main body is shaped like a standard syringe, apart from having a tapered end with a plastic “safeguard” attached, but has no threads on the tip to screw on the needle. The LeEject 2 Syringe is mostly made of chrome plated brass with the exception of the harpoon and piston rod, which is made of stainless steel.

The LeEject 2 Syringe is sold non-sterile, uses a standard 1.8mL anesthetic cartridge. The LeEject needles are EO sterilized, single use and sold separately.

Only the LeEject Needle can be used with the LeEject 2 Syringe.

Material Composition Table

Part	**Chemical Name**
Needle	Stainless steel
Needle Hub	Polypropylene
Needle Cap	Polypropylene
Dental Syringe	Chrome Plated Brass and stainless steel
Plastic Guard	Mineral Reinforced Nylon Resin (version 3-black)

DEVICE INDICATIONS FOR USE

LeEject 2 Syringe and Needle System is indicated to be used in conjunction with the LeEject needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.

COMPARISON OF TECHNICAL CHARACTERISTICS

Syringe Comparison

Parameter	Subject Device	Predicate Device
510(k) Number	K171254	K083796
Intended Use:	LeEject 2 Syringe and Needle System is indicated to be used in conjunction with the LeEject needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.	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.
Syringe Type	Cartridge Syringe	Cartridge Syringe
Principle of Operation	Manual	Manual
Specific Drug Use	Pre-filled local anesthetics cartridge 1.8 mL	Pre-filled local anesthetics cartridge 1.8 cc
Length	14.6 cm	13.2 cm
Diameter	1.25 cm	1.2 cm
Tip Type	Side-loading	Screw

Volume	1.8 mL Pre-filled anesthetic cartridge	1.8 cc Pre-filled anesthetic cartridge
Barrel Transparency	Dentist can observe cartridge during use	Dentist can observe cartridge during use
Material Used	Chrome Plated Brass, Stainless steel	Chrome Plated Brass Stainless steel
Sterility upon sales	Non-sterile	Non-sterile
Reusable	Yes	Yes
Validated Cleaning Method	Yes	Yes
Validated Sterilization Method	Yes	Unknown

Dental Needle Comparison

Element of Comparison for Dental Needle	Subject Device	Biodent
510(k) Number	Exempt	Exempt
Product Code	DZM	DZM
CFR	§872.4730	§872.4730
Intended Use	The LeEject dental needle is a double-pointed needle with plastic needle hub to be inserted and secured inside the LeEject 2 Syringe and to inject local anesthetics. The LeEject dental needles are available as individually packaged, sterile, and single use.	A dental needle is a double-pointed needle with plastic needle hub intended to be attached onto a dental syringe and to inject local anesthetics. The short needle penetrates the diaphragm of a pre-filled cartridge and the long needle is for parenteral use. The dental needles are available as individually packaged, sterile, and single use.
Gauge and Length	27 G Long 27 G x 35 mm	27 G Long 27 G x 35 mm

	27 G Short 27 G x 25 mm 30 G Short 30 G x 25 mm 30 G X-Short 30 G x 12 mm	27 G Short 27 G x 25 mm 30 G Short 30 G x 25 mm 30 G X-Short 30 G x 12 mm
Gauge	27G-L 27G-S 30G-S 30G-XS	27G-L 27G-S 30G-S 30G-XS
Tip Configuration	Tri-bevel Point	Tri-bevel Point
Cover Dimensions	1.0 x 7.6 cm	1.0 x 8 cm
Cover Color	27G /30G needle hubs are yellow/blue in color, respectively, and are seen through translucent needle caps. Sterility seals are labeled with size and color coded: Red, Brown, Violet, and Blue on the outside of the cover.	27G /30G needle hubs are yellow/blue in color, respectively, and are seen through translucent needle caps. Sterility seals are labeled with size and color coded: Red, Brown, Violet, and Blue on the outside of the cover.
Cover Strength	Made of polypropylene	Made of polypropylene
Hub/Needle Bond Strength	Epoxy glue; >2 kg in push or pull	Epoxy glue >2 kg in push or pull
Materials	Stainless Steel Needle with Polypropylene Hub	Stainless Steel Needle with Polypropylene Hub
Biocompatibility	Excellent	Excellent

12.1 Similarities and Differences

The LeEject 2 Syringe has equivalent Indications for Use, Intended Use, and material choice for the syringe as the predicate dental syringe. In addition, the LeEject 2 Syringe has a plastic Safeguard which is made of mineral reinforced nylon resin. Both are sold non-sterile with validated cleaning and sterilization methods.

The LeEject Needle has equivalent indications for use, intended use, materials, needle style, and is EO sterilized as the predicate.

The technological characteristics are substantially similar. The differences between the new device and the predicate device are:

- The new device has a different tip design which allows side loading of the needle onto the LeEject 2 Syringe versus the predicate's traditional screw-on tip. The LeEject dental needle, once inserted into the side opening of the syringe, is secured by our "safeguard" versus screwing the needle to the syringe. Both systems provide a secured attachment of the dental needle to the dental syringe and are substantially equivalent.

- The LeEject 2 Syringe and Needle System gives the user the option of recapping the dental needle or unlocking the "Safeguard" and allow the needle to fall into the sharps container without recapping. The predicate device requires recapping and unscrewing of the dental needle prior to disposal into a sharps container. Both dental syringes allow for recapping prior to disposal and are substantially equivalent.

These differences raise no new questions concerning safety or effectiveness. The LeEject 2 Syringe and Needle System is substantially equivalent to the predicate device.

PERFORMANCE DATA

Nonclinical Testing

- ISO 9626:1991/Amd.1:2001(E), Section 10 and Annex D:" Resistance to Breakage and Custom Needle Deflection"
- AAMI TIR12:2010. "Designing, testing and labeling reusable medical devices for reprocessing in health care facilities. A guide for medical device manufacturers."
- ANSI/AAMI/ISO 17665-1:2006, "Sterilization of health care products – Moist heat-Part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices"
- ANSI/AAMI/ISO 11135:2007, "Sterilization of healthcare products: Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices."

- EN 556-1: 2001, Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices.
- EN 1174:1996, “Sterilization of medical devise. Estimation of the population of micro-organisms on product. Requirements.”
- EN 866:1997, “Biological systems for testing sterilizers and sterilization processes. General requirements”
- ISO 10993-7:2008, Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals”
- ANSI/AAMI/ISO 11607:2006. “Packaging for Terminally Sterilized Medical Devices”
- ISO 14971 Second Edition 2007-03-01. Medical Devices – Application of risk management to Medical devices
- ANSI/AAMI/ISO 14937:2009/(R)2013, Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilization process for medical devices.
- ANSI/AAMI ST79: 2010 /A4:2013 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- ANSI/AAMI ST81:2004 (R) 2010. Sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F 1980:2011. Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 10993-5: 2009 / (R) 2014 (GLP) Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity
- ISO 10993-10: 2010/ (R) 2014. Tests for irritation and delayed type hypersensitivity

Clinical testing was not performed with this device.

CONCLUSION

The LeEject 2 Syringe and Needle System meets the functional claims and intended use as described in the product labeling. The proposed device, the LeEject 2 Syringe and Needle System is substantially equivalent to the predicate devices, Miltex Dental Aspirating Syringe and Biodent dental needles.