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5 510(k) SUMMARY

K101717

AUG 2 0 2010

Aerobine Line of Dental Handpieces

Submitted by: Aerobine, Inc.
7670 Opportunity Rd. Suite 100
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Date of Summary: March 9, 2010

Common name: Air-powered Dental Handpiece

Device name: Aerobine Line of Dental Handpieces: Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, AeroBreeze Mini, Karam45, Dexor45, Karam 4B coupling, Karam 2A coupling

Classification: Dental Handpiece and Accessories
Class I Medical Device: 21 CFR 872.4200
Product Code: EFB
Panel 72

Predicate Devices: JINDELL Highspeed Air Turbine Handpiece (K062740)
Product Code: EFB

IMPACT Air 45 Handpiece for Periodontal Use (K972376)
Product Code: EFB

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5.1 Device Description

The devices are an air-powered dental handpieces intended for use with a friction-grip bur that conforms to ISO 1797-1 standard. Recommended air pressure is 29 ~ 36 psig (gage pressure) to produce high-speed bur rotation ranging between 380,000 and 450,000 RPM. Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, and AeroBreeze Mini models are straight-headed. Karam45 and Dexor45 models are designed with a 45-degree back angle. The devices include a water line that directs water mist/jet to the cutting area for cooling and irrigation.

5.2 Indications for use

Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, and AeroBreeze Mini models are air-powered highspeed dental handpieces with intended use of preparing dental cavities for restorations, such as fillings, reducing hard tooth structure, and cleaning teeth. Karam STD, Karam Mini, AeroBreeze STD, and AeroBreeze Mini can be used with either Type B (Karam 4B) or Type A (Karam 2A) coupling. Karam ECN model connects directly to either Type A or Type B hose connectors and does not require a coupling.

Karam45 and Dexor45 are air-powered highspeed dental handpieces with intended use of being a surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used. Both models can be used with either Type B (Karam 4B) or Type A (Karam 2A) coupling.

5.3 Description of device design

Aerobine line of handpieces employs a cartridge type air turbine with a common core design across the product line. All models employ a friction-grip push button chuck, a drive air line, a discharge air egress line, a water delivery line to supply cooling water. With the exception of Karam ECN, all models can be used with either Karam 4B or Karam 2A coupling. Karam ECN connects directly to Type A or Type B hose connectors without a coupling. Comparison of device technological characteristics relative to predicate devices is made in Table 1.

5.4 Conclusions from Technical Comparisons with predicate devices

Based on technological profile comparisons (Table 1) and engineering analysis results obtained in support of the sterilization validation effort (section 14), we conclude:

- Aerobine Handpieces, Karam STD/Mini/ECN, AeroBreeze STD/Mini are substantially equivalent to the predicate device (K062740) in terms of their intended use, operating principles, performance, material compositions, and sterilization characteristics.

- Aerobine Handpieces, Karam45, Dexor45 are substantially equivalent to the predicate device (K972376) in terms of their intended use, operating principles, performance, material compositions, and sterilization characteristics.

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- Aerobine Line of Dental Handpieces (Model: Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, AeroBreeze Mini, Karam45, Dexor45, Karam 4B coupling, Karam 2A coupling) are both safe and effective for their intended use.

Table 1 Technological Characteristics Comparisons

Technological Characteristics	**Karam STD/Mini/ECN, AeroBreeze STD/Mini**	**Comparison to Predicate Device** (K062740)	**Karam45. Dexor45**	**Comparison to Predicate Device** (K972376)
Indication For Use	For restoration and cavity preparation	Identical	For surgical procedures such as 3rd molar removal	Identical
Energy source	Compressed air	Identical	Compressed air	Identical
Design	Cartridge type turbine, friction-grip push-button chuck, cooling water delivery system, couplings	Identical	Cartridge type turbine, friction-grip push-button chuck, cooling water delivery system, couplings, rear air bleed for improved infection control	Identical Except: non-catridge type turbine
Minimum Performance requirements	Speed range, stall torque, cooling water flow rate, noise level, bur extraction force, eccentricity	Identical	Speed range, stall torque, cooling water flow rate, noise level, bur extraction force, eccentricity	Identical
Standards met	EN ISO 7785-1 ISO 9168 ISO 1797-1	Identical	EN ISO 7785-1 ISO 9168 ISO 1797-1	Identical
Composition of Materials	Stainless steel, aluminum alloy, copper alloy, chrome plating, nickel plating, elastomer	Identical	Stainless steel, aluminum alloy, copper alloy, chrome plating, nickel plating, elastomer	Identical
Biocompatibility	Constructed from usual and common materials known to the industry	Identical	Constructed from usual and common materials known to the industry	Identical
Sterility	Autoclave up to 135°C 15 minutes at 134 °C	Unknown	Autoclave up to 135°C 15 minutes at 134 °C	Autoclave up to 135°C 20 minutes at 135 °C
Electrical Safety	No electrical connection	Identical	No electrical connection	Optional fiber-optic
Chemical Safety	Used corrosion-resistant materials, free of chemical hazard	Identical	Used corrosion-resistant materials, free of chemical hazard	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aerobine, Incorporated
C/O Ms. Paula Wilkerson
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

AUG 2 0 2010

Re: K101717
Trade/Device Name: Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, AeroBreeze Mini, Karam45, Dexor45, Karam 4B coupling, and Karam 2A coupling
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: August 5, 2010
Received: August 6, 2010

Dear Ms. Wilkerson:

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,

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

K101717 181

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4 Indications for Use

510(k) Number (if known):

Device Names: Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, AeroBreeze Mini, Karam45, Dexor45, Karam 4B coupling, and Karam 2A coupling

Indications For Use:

Karam STD, Karam Mini, Karam ECN, AeroBreeze STD, and AeroBreeze Mini models are air-powered highspeed dental handpieces with intended use of preparing dental cavities for restorations, such as fillings, reducing hard tooth structure, and cleaning teeth. Karam STD, Karam Mini, AeroBreeze STD, and AeroBreeze Mini can be used with either Type B (Karam 4B) or Type A (Karam 2A) coupling. Karam ECN model connects directly to either Type A or Type B hose connectors and does not require a coupling.

Karam45 and Dexor45 are air-powered highspeed dental handpieces with intended use of being a surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used. Both models can be used with either Type B (Karam 4B) or Type A (Karam 2A) coupling.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Ken Hinkley for MSR

Concurrence of CDRH, Office of Device Evaluation (ODE) (Division Sign-Off)
Page 1 of 1

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K101717