JUN 2 9 2012

510(k) Summary

"This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K120218 (applicant leave blank)

Company:

Submitter's name:	Palm Beach Dental Supply d/b/a TEK USA
Submitter's address:	1635 SW 15th St Pompano Beach, FL 33069
Phone number:	954-943-0565
Fax number:	954-941-7137
Name of contact:	David White

Proprietary/Trade Name:

Device name:	Air powered dental handpiece
Proprietary/Trade name:	TEK USA Airdriven LED Handpiece with Integrated E- generator
Common name:	Dental handpiece

Classification:

Classification name:	Dental Handpiece and Accessories
Device Classification :	I
Regulation Number:	21CFR 872.4200
Panel:	Dental
Product Code:	EFB ("Handpiece, Airpowered, Dental")

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Predicate Device:

Predicate 510(k): K082716
Trade name: W&H Alegra Air-Driven Highspeed Handpiece
Product Code: EFB ("Handpiece, Airpowered, Dental")

Device Description:

Device Description: TEK USA Airdriven LED Handpiece with Integrated E- generator

Intended Use:

Device Intended Use: The TEK USA Airdriven LED Handpiece with Integrated E-Generator is indicated for use by a trained dental professional authorized in the practice of general dentistry. These dental handpiece devices are available in both high and low speed and are designed for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations/restorations, polishing teeth and other procedures that are considered within the space of dental prophylaxis.

Technological Characteristics:

The TEK USA Airdriven LED Handpiece with Integrated E- generator is compared directly to the predicate device:

Substantial Equivalence Comparison Summary Table

Predicate Device & 510(k) Number: W&H Alegra Air-Driven Highspeed Handpiece (k082716) Predicate device promotional materials are attached in section 11.0	
Technological Characteristics	***Comparison Result***
Indication for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical Safety	Similar
Anatomical sites	Similar
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment/other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Not applicable

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Radiation safety	Not applicable

Note: As noted in the above *Substantial Equivalence Comparison Summary Table* similarity with sterility is based on use of an FDA cleared table top autoclave sterilizer as detailed in K021504. The parameters for use with this device are as follows:

Recommended Use	Sterilization Time	Sterilization Temp	Drying Time
Unwrapped handpiece	3.5 mins	134° C (273°F)	0 mins
Wrapped handpiece (mylar/tyvek pouch)	8 mins	134° C (273°F)	20 mins

Substantial equivalence:

The TEK USA Airdriven LED Handpiece with Integrated E- generator successfully meets the following international standards:

- ***ISO 13485: 2003 + AC:2007:*** *"the international standard for Medical devices — Quality management systems — Requirements for regulatory purposes."* Version 2007
- ***ISO 1797-1:*** "Dental rotary instruments. Shanks. Shanks made of metals" Version 1995
- ***ISO 9168:*** "Specification for screw gauge limits and tolerances. Gauges for ISO metric screw threads" Version 1968
- ***EU Medical Devices Directive, ref 93/42/EEC (incl 2007/47/EC):*** Version 2007
- ***ISO 13402*** : "Surgical and dental hand instruments. Determination of resistance against autoclaving, corrosion and thermal exposure" Version 1995
- ***ISO 14971:*** "Medical device risk management" Version 2007
- ***ISO 10993-1:*** "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" Version 2009
- ***ISO 10993-5:*** "Biological evaluation of medical devices: Evaluation and testing within a risk management process" Version 1999
- ***ISO 10993-10:*** "Biological evaluation of medical devices: Tests for irritation and skin sensitization" Version 2010
- ***EN 1041:*** "Information supplied by manufactures of medical devices"
- ***ISO 9687:*** "Dental equipment. Graphical symbols" Version 1993
- ***EN 980:*** "Graphical symbols for use in the labeling of medical devices" Version 1997

Clinical Data:

Clinical data is not needed for most dental handpieces cleared by the 510(k) process.

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Conclusions:

It can be concluded that the TEK USA Airdriven LED Handpiece with Integrated E- generator meets the ASTM or equivalent (ISO) standards such that the device demonstrates substantial equivalence to the W&H Alegra Air-Driven Highspeed Handpiece (k082716) predicate device.

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

Palm Beach Dental Supply d/b/a TEK USA
C/O Mr. Michael Calhoun
Calhoun and Associates
2700 NE 24th Street
Pompano Beach, Florida 33069

JUN 29 2012

Re: K120218
Trade/Device Name: TEK USA Airdriven LED Handpiece with Integrated E-Generator
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: June 7, 2012
Received: June 13, 2012

Dear Mr. Calhoun:

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

Indications for Use

510(k) Number (if known): K120218

Device Name: TEK USA Airdriven LED handpiece with Integrated E-Generator

Indications For Use:

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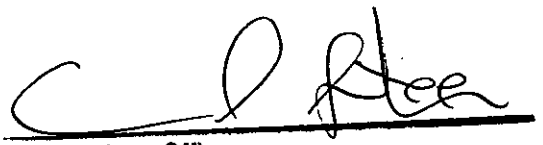
Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K120218