



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 15 2009

Mr. Thomas H. Louisell  
Regulatory Compliance Manager  
A-dec, Incorporated  
2601 Crestview Drive  
Newberg, Oregon 97132-9257

Re: K082716

Trade/Device Name: A-dec/W&H Alegra Air-Driven Highspeed Handpiece, Models  
TE-98, TE-97 A-dec/W&H Alegra Handpiece Attachment,  
Models WE-99 LED G, WE-66 LED G, WE-57 LED G,  
WE-56 LED G, HE-43A

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece and Accessories

Regulatory Class: II

Product Code: EFB

Dated: January 6, 2009

Received: January 7, 2009

Dear Mr. Louisell:

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 Division 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): K082716

Device Name:

A-dec/W&H Alegra Air-Driven Highspeed Handpiece, models TE-98, TE-97  
A-dec/W&H Alegra Handpiece Attachment, models WE-99 LED G, WE-66 LED G, WE-57  
LED G, WE-56 LED G, HE-43 A

Indications For Use:

The A-dec/W&H Alegra Air-Driven Highspeed Handpiece is an air-powered dental handpiece for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth.

The A-dec/W&H Alegra Handpiece Attachment is powered by either an air-motor or electric micromotor for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801 Subpart D)

OR Swan Punne Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K082716