DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 23, 2015

W & H Dentalwerk Buermoos GmbH
Mag. Anja Lindner
Manager Regulatory Affairs
Ignaz-Glaser-Strasse 53
A 5111 Buermoos
AUSTRIA

Re: K143704
Trade/Device Name: Advanced Air System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: October 12, 2015
Received: October 14, 2015

Dear Mag. Anja Lindner:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) number: K143704

Device Name: Advanced Air System

Indication for Use: Pneumatic drive system for dental handpieces and dental air motors, which is intended to be used in general dental applications such as: removal of decayed materials, cavities and crown preparations, removal of filings, finishing of tooth and restauration surfaces, polishing, prophylaxis and endodontics.

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K143704

# 510(k) SUMMARY

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| Applicant and Owner | W & H DENTALWERK BÜRMOOS GMBH<br>Ignaz-Glaser-Strasse 53<br>A - 5111 Bürmoos<br>Austria<br>Tel.: 0043 -6274 / 6236 -397<br>Fax: 0043 -6274 / 6236 -55 |
| Registration Number | 9681479 |
| Contact Person | Mag. Anja LINDNER |
| Date of Submission | 19th of December, 2014 |
| Device Name | Advanced Air System |
| Classification Name | Handpiece, Air-powered, Dental |
| Regulation Number | 21 CFR 872.4200 class 1 reserve |
| Product Code | EFB |
| Predicate Devices | Primary Predicate:<br>"Axis System", Dentsply / York, PA; cleared under K072989<br><br>Reference Predicates:<br>"A-dec/W&H Synea Air-Driven Highspeed Handpiece and Attachment", W&H Dentalwerk, Bürmoos; cleared under K070663<br><br>„A-dec/W&H Alegra Air-Driven Highspeed Handpiece and Attachment", W&H Dentalwerk, Bürmoos; cleared under K082716 |
| Device Description | The Advanced Air System is intended for dental transmission instruments used in the field of preventive dentistry, restorative dentistry such as cavity preparation and prosthodontics such as crown preparation and endodontics.<br><br>The system consists of the control unit (AC-1.0), which is designed to be built in a dental chair. As an attachment the air-driven handpiece (RK-97 L, RG- 97 L, and/or RK-94 L) or the air motor (RM-25 L RM) can be used.<br><br>The air-driven handpiece is equipped with a speed sensor, which is connected to a control module that regulates the applied air pressure to the handpiece through a proportional valve in order to maintain constant speed throughout the dental treatment. |

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| Indication for Use: | Pneumatic drive system for dental handpieces and dental air motors, which is intended to be used in general dental applications such as: removal of decayed materials, cavities and crown preparations, removal of filings, finishing of tooth and restauration surfaces, polishing, prophylaxis and endodontics. |

Technological Characteristics

Control unit:

| **Technological characteristic** | **Subject device** | **Predicate Device** Axis System (K072989) |
|---|---|---|
| User modes (control characteristics) | 3 | 1 |
| Supply air | 0.52 – 0.59 MPa (75 – 85 psi) | 0.45 – 0.52 MPa (65 – 75 psi) |
| Power supply | 19–29 V AC @ 50-60Hz or 24–40 V DC | 24 V DC |

The subject device and the predicate device, both contain a proportional air valve which regulates the amount of air flow to the straight air-powered handpiece or airmotor according to the received speed signal.
Both devices are equipped with a speed sensor. The speed sensor of the subject device is positioned in the head area - therefore the speed is directly measured where the rotation occurs.
The speed sensor of the predicate device is positioned in the coupling area where it measures the frequency of vibrations of the rotating bur and concludes to the speed.

Straight air-powered Handpieces and Air Motor:

| **Technological characteristic** | **Subject devices** (RK-97L, RG-97 L, RK-94 L, RM-25 L RM) | **Reference Predicate Devices** TA-97 LED, AM-25 L RM (K070663, K082716) |
|---|---|---|
| Optic lighting | yes | yes |
| Speed range | RK/RG-97 L: 60,000–320,000 rpm<br>RK-94 L: 60,000–320,000 rpm<br>RM-25 L RM: 2,000–20,000 rpm | TA-97 LED: 400,000 rpm<br>AM-25 L RM: 5,000–25,000 rpm |
| Max. torque | RK/RG-97 L: 2.4 Nmm (0.34 ozf in)<br>RK-94 L: 1.5 Nmm (0.21 ozf in)<br>RM-25 L RM: 44 Nmm (6.2 ozf in) | TA-97 LED: 1.7 Nmm (0.25 ozf in)<br>AM-25 L RM: 24 Nmm (3,4 ozf in) |
| Max. power | RK/RG-97 L: 30 W<br>RK-94 L: 20 W<br>RM-25 L RM: 28 W | TA-97 LED: 18 W<br>AM-25 L RM: 16 W |
| Toque limit | 30 100 % | None |
| Max. air consumption | RK/RG-97 L: 1.2 l/s (2.5 cfm)<br>RK-94 L: 1.1 l/s (2.3 cfm)<br>RM-25 L RM: 1.5 l/s (3.2 cfm) | TA-97 LED: 0.75 l/s (1.5 cfm)<br>AM-25 L RM: 1 l/s (2.1 cfm) |
| Weight | RK/RG-97 L: 38 g (1.34 oz)<br>RK-94 L: 39 g (1.34 oz) | TA-97 LED: 38 g (1.34 oz) |

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| | The subject device includes a speed sensor; the other aspects of the construction of the subject device and the predicate device are identical.<br><br>The technical principle is the same as within the predicate device.<br>The main technological characteristics are the same or, at least, quite similar to those of the comparable product. |
| Comparison of the device to the predicate device | The target field of application, the intended use, functions and technological features, performance parameter and material are the same or, at least, quite similar to those of the predicate device.<br>The product comparison did not raise new or different questions of equivalence.<br>The new device is substantially equivalent to the predicate device. |
| Performance Testing | Electrical Safety Tests according to IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br><br>Electromagnetic Compatibility Test according to IEC 60601-1-1:2007: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests<br><br>Product testing of handpiece function and life cycle testing were performed per ISO 14457:2012: *Dentistry – Handpieces and Motors.* The results demonstrate substantial equivalence in this regard.<br><br>Software validation according to IEC 62304:2006: Medical device software – Part 1: Guidance on the application of ISO 14972 to medical device software<br><br>Usability validation according to the standard IEC 62366:2007<br><br>Thermal safety according to the standard IEC 62471:2006: Photobiological safety of lamps and lamp systems<br><br>Evaluation of biocompatibility is based upon the fact that patient contacting materials in the subject handpiece are identical to those in the previously W&H TA-97LED and AM-25L RM handpieces, which, as handpieces, present the same level and duration of contact. In addition, Cytotoxicity Testing per EN ISO 10993-5:2009-06 was performed. This evaluation meets the requirements of ISO 7405:2008 for preclinical evaluation of biocompatibility of dental devices. |
| Clinical Testing | Clinical data were not needed for this new product. |

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| Conclusion | W&H considers the Advanced Air System to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in intended use, principles of operation, functional design, and established medical use. Differences between the devices shown in the side-by-side comparison table above are minor and do not have any negative effect on equivalence.<br><br>The "Advanced Air System", as designed and manufactured, is substantially equivalent to its predicate device. |