



Food and Drug Administration  
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February 23, 2017

W&H Dentalwerk Bürmoos GmbH  
Anja Lindner  
Mag., Regulatory Affairs  
Ignaz-Glaser-Straße 53  
Bürmoos, Salzburg 5111  
Austria

Re: K162926

Trade/Device Name: W&H Air-Powered Handpieces And Handpiece Attachments  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental Handpiece and Accessories  
Regulatory Class: Class I  
Product Code: EFB  
Dated: January 20, 2017  
Received: January 25, 2017

Dear 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,

 Michael J. Ryan -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

## Indications for Use

510(k) number:

K162926

Device Name:

W&H Air-Powered Handpieces and  
Handpiece Attachments

Indication for Use:

The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.

The dental handpiece/contra-angle is intended for the following applications: Removal of decayed materials, cavities and crown cement, removal of fillings, finishing and polishing of tooth and restoration surfaces.

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)

### 510(k) SUMMARY

Submitter	W & H DENTALWERK BÜRMOOS GMBH Ignaz-Glaser-Strasse 53 A - 5111 Bürmoos Austria Tel.: 0043 -6274 / 6236 -397 Fax: 0043 -6274 / 6236 -55
Registration Number	9681479
Contact Person	Mag. Anja LINDNER
Date of Submission	23 <sup>rd</sup> of February, 2017
Device Name	W&H Air-Powered Handpieces and Handpiece Attachments
Classification Name	Dental handpiece and accessories
Usual/Common Name	Handpiece, Air-Powered, Dental
Regulation Number	21 CFR 872.4200
Regulatory class	I
Product Code	EFB
Predicate Devices	<p><b><u>Primary Predicate:</u></b>          “Advanced Air System”, W&amp;H Dentalwerk Bürmoos GmbH; cleared under K143704.</p> <p><b><u>Reference Predicates:</u></b>          “A-dec/W&amp;H Synea Air-Driven Highspeed Handpiece,          “A-dec/W&amp;H Synea Handpiece Attachment” cleared under K070663</p> <p>The predicates have not been subject to a design-related recall.</p>



**W&H Air-Powered Handpieces and  
Handpiece Attachments  
510(k) Summary**

<p>Device Description and Technological Characteristics</p>	<p>The Air-Powered Handpieces and the Handpiece Attachments are reusable, ergonomically shaped and some of them include LED light system.</p> <p>The submission is comprised of:</p> <ul style="list-style-type: none"> <li>• The <b>W&amp;H Synea Vision/Fusion</b> Air-Powered Handpieces: TK-100 L, TK-100 LM, TK-98 L, TK-98 LM, TK-97 L, TK-97 LM, TK-94 L, TK-94 LM, TG-97, TG-97 L, TG-97 LM, TG-97 L RM, TG-97 L N, TG-98, TG-98 L RM, TG-98 LM, TG-98 L N</li> <li>• The <b>W&amp;H Alegria</b> Air-Powered Handpieces: TE-97 LQ, TE-98 LQ, TE-95 RM, TE-97, TE-97 RM, TE-98, TE-98 RM</li> <li>• The <b>W&amp;H Air Motors</b>: AM-25 A RM, AM-25 E RM, AM-25 RM, AM-20 E RM, AM-20 RM</li> <li>• The <b>W&amp;H Roto Quick</b> couplings: RQ-04, RQ-14, RQ-24, RQ-34, RQ-54, RM-34 LED G</li> <li>• The <b>W&amp;H Synea Fusion</b> Handpiece Attachments: HG-43 A, WG-56 LT, WG-56 A, WG-66 LT, WG-66 A, WG-99 LT, WG-99 A</li> <li>• The <b>W&amp;H Synea Vision</b> Handpiece Attachments: HK-43 LT, WK-99 LT, WK-99 LT S, WK-93 LT S, WK-93 LT, WK-56 LT, WK-56 LT S, WK-66 LT, WK-66 LT S</li> <li>• The <b>W&amp;H Alegria</b> Handpiece Attachments: HE-43, HE-43 T, WE-56, WE-57, WE-57 T, WE-56 LED G, WE-66 LED G, WE-99 LED G</li> </ul> <p>The Air-powered Handpieces contain pipes inside which supply air for driving the turbine’s impeller as well as supply air and water for creating spray exhausting through 3, 4 or 5 ports located in the handpiece’s head and intended for cooling the working area as well as the rotating bur. Depending on the type of handpiece – the handle might contain an integrated circuit board and wire bundles, for supplying current and voltage to a head-sided assembled LED light source.</p> <p>The Handpiece Attachments also contain pipes inside which supply air and water for spray exhausting and for cooling the working area as well as the rotating bur.</p> <p>Depending on the type of handpiece – the handle might contain an integrated circuit board and wire bundles, for</p>
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# W&H Air-Powered Handpieces and Handpiece Attachments

## 510(k) Summary

	supplying current and voltage to a head-sided assembled LED light source.																										
Indications for Use:	<p>The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.</p> <p>The dental handpiece/contra-angle is intended for the following applications: Removal of decayed materials, cavities and crown cement, removal of fillings, finishing and polishing of tooth and restoration surfaces.</p>																										
Comparison of the device to the predicate device	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 25%; text-align: center;">Predicate Device K143704</th> <th colspan="2" style="width: 55%; text-align: center;">New Device</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Intended Use</td> <td> <b>Advanced Air System:</b>                       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 fillings, finishing of tooth and restoration surfaces, polishing, prophylaxis and endodontics.                 </td> <td> <b>Air-Powered Handpieces:</b>                       The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.                 </td> <td style="text-align: center;">Similar*</td> </tr> <tr> <td style="text-align: center;">Speed</td> <td>RK-97 L: 400,000 RK-94 L: 410,000</td> <td>TK-94 L: 410,000 TK-98 L: 360,000 TK-100 L: 330,000 TE-97 LQ: 390,000</td> <td style="text-align: center;">Similar</td> </tr> <tr> <td style="text-align: center;">Operating pressure</td> <td>RK-97 L: 3±0.3 RK-94 L: 3±0.3</td> <td>TK-94 L: 3±0.3 TK-98 L: 3±0.3 TK-100 L: 3±0.3 TE-97 LQ: 2.2 – 2.8</td> <td style="text-align: center;">Same</td> </tr> <tr> <td style="text-align: center;">Current consumption</td> <td>RK-97 L: 0.4 A RK-94 L: 0.4 A</td> <td>TK-94 L: 0.4 A TK-98 L: 0.4 A TK-100 L: 0.4 A TE-97 LQ: 0.4 A</td> <td style="text-align: center;">Same</td> </tr> <tr> <td style="text-align: center;">Air consumption</td> <td>RK-97 L: 45 NI/min RK-94 L: 75 NI/min</td> <td>TK-94 L: 45 NI/min TK-98 L: 50 NI/min TK-100 L: 50 NI/min TE-97 LQ: 50 NI/min</td> <td style="text-align: center;">Similar**</td> </tr> </tbody> </table> <p>*The Indications for Use of the Advanced Air System is a combination of the Indications for Use of the Air-Powered Handpieces and the Air Motor and therefore similar.</p> <p>**The new Air-Powered Handpieces are identical to the older versions; the main difference is that the new ones cannot be sensor controlled.</p>				Predicate Device K143704	New Device		Intended Use	<b>Advanced Air System:</b>  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 fillings, finishing of tooth and restoration surfaces, polishing, prophylaxis and endodontics.	<b>Air-Powered Handpieces:</b>  The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.	Similar*	Speed	RK-97 L: 400,000 RK-94 L: 410,000	TK-94 L: 410,000 TK-98 L: 360,000 TK-100 L: 330,000 TE-97 LQ: 390,000	Similar	Operating pressure	RK-97 L: 3±0.3 RK-94 L: 3±0.3	TK-94 L: 3±0.3 TK-98 L: 3±0.3 TK-100 L: 3±0.3 TE-97 LQ: 2.2 – 2.8	Same	Current consumption	RK-97 L: 0.4 A RK-94 L: 0.4 A	TK-94 L: 0.4 A TK-98 L: 0.4 A TK-100 L: 0.4 A TE-97 LQ: 0.4 A	Same	Air consumption	RK-97 L: 45 NI/min RK-94 L: 75 NI/min	TK-94 L: 45 NI/min TK-98 L: 50 NI/min TK-100 L: 50 NI/min TE-97 LQ: 50 NI/min	Similar**
	Predicate Device K143704	New Device																									
Intended Use	<b>Advanced Air System:</b>  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 fillings, finishing of tooth and restoration surfaces, polishing, prophylaxis and endodontics.	<b>Air-Powered Handpieces:</b>  The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.	Similar*																								
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# W&H Air-Powered Handpieces and Handpiece Attachments

## 510(k) Summary

	<b>Predicate Device K070663</b>	<b>New Device</b>	
Intended Use	<b>A-dec/W&amp;H Synea Handpiece Attachment:</b>  The straight and contra-angle handpiece is intended for the cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filling and polishing.	<b>Handpiece Attachment:</b>  The dental straight/contra-angle handpiece is intended for the following applications: Removal of decayed materials cavities and crown cement, removal of fillings, finishing and polishing of tooth and restoration surfaces.	Same
Speed (rpm)	WA-66 LT: 40,000 WA-99 LT: 40,000 HA-43 LT: 40,000	WG-56 LT: 40,000 WK-99 LT: 40,000 HK-43 LT: 40,000	Same
Spray flow rate	WA-66 LT: >50 ml/min WA-99 LT: >50 ml/min HA-43 LT: >50 ml/min	WG-56 LT: >50 ml/min WK-99 LT: >50 ml/min HK-43 LT: >50 ml/min	Same
Chip air setting range (bar)	WA-66 LT: 1.5 - 3 WA-99 LT: 1.5 - 3 HA-43 LT: 1.5 - 3	WG-56 LT: 1.5 - 3 WK-99 LT: 1.5 - 3 HK-43 LT: 1.5 - 3	Same
Water setting range (bar)	WA-66 LT: 0.5 – 2 WA-99 LT: 0.5 – 2 HA-43 LT: 0.5 – 2	WG-56 LT: 0.5 - 2 WK-99 LT: 0.5 - 2 HK-43 LT: 0.5 - 2	Same
Dental bur shank diameter	WA-66 LT: 2.35 mm WA-99 LT: 1.6 mm HA-43 LT: 2.35 mm	WG-56 LT: 2.35 mm WK-99 LT: 1.6 mm HK-43 LT: 2.35 mm	Same
<b>Predicate Device K143704</b>			
	<b>Air Motor RM-25 L RM</b>	<b>New Device  Air Motor AM-20 RM</b>	
Intended Use	The air motor is intended for the following applications: Drive for dental transmission instrument for dental restoration, prophylaxis and root canal preparation. Supply of dental transmission instruments with cooling air, chip air, spray water and light.	The air motor is intended for the following applications: Drive for dental transmission instruments for dental restoration and prophylaxis. Supply of dental transmission instruments with cooling air, chip air, spray water and light.	Same
Speed	5,000 – 25,000	5,000 - 25,000	Same



# W&H Air-Powered Handpieces and Handpiece Attachments

## 510(k) Summary

Operating pressure	1.5 – 2.5 bar	2.2 – 3 bar	Similar
Current consumption	0.7 A	N/A	Different*
Air consumption	42 – 51 NI/min	42 – 50 NI/min	Same
Length	87,87 mm	80 mm	Similar
Diameter	20 mm	18 mm	Similar**

\*no current consumption because the new models are not sensor controlled  
 \*\*Smaller diameter to be compatible with new handpieces

### Hygiene / Maintenance – Air-Powered Handpieces and Handpiece Attachments

Item	Predicate devices (K143704 and K070663)	New device	Differences
Lubrication	after max. 30 minutes of use	after max. 30 minutes of use	None
Cleaning	rinse under demineralized water (< 38°C/100°F) with aid of brush	rinse under demineralized water (< 38°C/100°F) with aid of brush	None
Sterilization	Dynamic-air-removal sterilizers: 270°F (132°C) for 4 minutes or  Gravity displacement sterilizers: 270°F (132°C) for 15 minutes	Dynamic-air-removal sterilizers: 270°F (132°C) for 4 minutes or  Gravity displacement sterilizers: 270°F (132°C) for 15 minutes	None

**Conclusion:**

The target field of application, the intended use, functions and technological features, performance parameter are the same or, at least, quite similar to those of the predicate device.

The product comparison did not raise new or different questions regarding substantial equivalence.

The new device is substantially equivalent to the predicate device.





**W&H Air-Powered Handpieces and  
Handpiece Attachments**  
510(k) Summary

<p>Performance Testing</p>	<p>Product testing of the handpieces function and life cycle testing were performed according to ISO 14457:2012: Dentistry – Handpieces and Motors. The results demonstrate substantial equivalence in this regard.</p> <p>EMC Testing according to IEC 60601-1-2:2007 Medical electrical equipment Part 1-2 General requirements... Electromagnetic Compatibility</p> <p>Thermal safety according to the standard IEC 62471:2006: Photobiological safety of lamps and lamp systems</p> <p>Evaluation of biocompatibility is based upon the fact that patient contacting materials in the subject handpiece are identical to those in the previously cleared predicates (K143704 and K070663), which as handpieces and handpiece attachments, present the same level and duration of contact. In addition, Cytotoxicity Testing per EN ISO 10993-5:2009 was performed. This evaluation meets the requirements of ISO 7405:2008 for preclinical evaluation of biocompatibility of dental devices.</p> <p>Various functionality and lifecycle tests as well as further bench tests demonstrate substantial equivalence.</p>
<p>Clinical Testing</p>	<p>Clinical data were not needed for this new product.</p>
<p>Conclusion</p>	<p>W&amp;H considers the Air-Powered Dental Handpieces and Handpiece Attachments to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in intended use, principles of operation, material composition, 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.</p>