DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 23, 2016

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

Re: K161957
Trade/Device Name: Implantmed SI-1015 incl. Accessories
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EBW

Dated: October 24, 2016
Received: October 27, 2016

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:

K161957

Device Name:

Implantmed SI-1015 incl. Accessories

Indication for Use:

Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.

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

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 Summary was Prepared	21st of November, 2016
Device Name	Implantmed SI-1015 incl. Accessories
Classification Name	Dental Handpiece and Accessories
Common/Usual Name	Controller, Foot, Handpiece and Cord
Regulation Number	21 CFR 872.4200
Regulatory class	I
Product Code	EBW
Predicate Devices	Primary Predicate: "Implantmed SI-915/923", W&H Dentalwerk Bürmoos GmbH; cleared under K052741 Reference devices for the accessories: "Osstell ISQ Implant Stability Meter", Osstell®; cleared via K082523 „Surgical contra-angle handpieces", W&H Dentalwerk, Bürmoos; cleared under K011061 and K080939 The predicate has not been subject to a design-related recall.

Device Description

The Implantmed SI-1015 is intended for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.

The new Implantmed SI-1015 is a redesigned version of the old one.

The submission consists of :

- the control unit,
- a motor with cable with or without light (EM-19 LC/EM-19),
- a wireless or wired foot control (S-NW or S-N2),
- the Osstell Module (SI-SQ)
- and as an attachment the surgical handpieces
- (WS-56 L, WS-75 L, WS-91 L, WS-92 L and S-11 L).

The user can select five different programs. Switching between these programs is performed by foot control or via touch display.

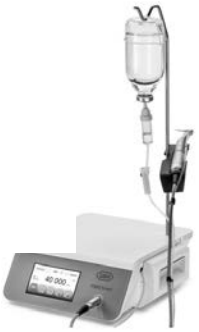
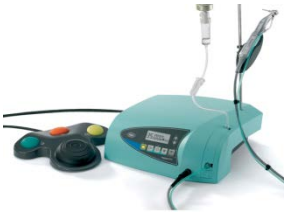
Programs 1-3 are used for adjusting the speed and programs 4-5 are for adjusting the torque.
The control unit is intended to be used with the EM-19 or EM-19 L motor.
The Implantmed SI-1015 will be delivered with software on the control unit.
To run the Implantmed SI-1015 according to its intended use, W&H provides five different **surgical handpieces**.

Type	Transmission ratio	Max. speed	Max. torque
WS-56 L	1:1	50,000	not applicable
WS-75 L	20:1	50,000	70 Ncm
WS-91 L	1:2.7	50,000	not applicable
WS-92 L	1:2.7	50,000	not applicable
S-11 L	1:1	50,000	not applicable

Indications for Use:

Implantmed SI-1015 (incl. EM-19/EM-19 L):

Mechanical drive unit with coolant supply for transmission instruments with ISO 3964
(DIN 13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.

Technological Characteristics	**General specification SI-1015 incl. Accessories**			
	Item	**New device**	**predicate device**	**Difference**
	Picture			-
	Name	Implantmed SI-1015	Implantmed SI-915/923	-
	Manufacturer	W&H Dentalwerk Bürmoos GmbH	W&H Dentalwerk Bürmoos GmbH	
	Where used	Dental practice, dental clinic	Dental practice, dental clinic	none
	Indications for use	Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN 13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.	Mechanical drive unit with coolant supply for transmission instruments with coupling system according to ISO 3964 (Din 13.940) The equipment is a drive unit for use in dental surgery, implantology and maxilla-facial surgery for treatment of dental hard tissue.	none
	Control Unit	Main dimensions: 100x262x291mm Front panel: TFT display with capacitive touch Programs: 5 programs for various stages of implantology Irrigation: 100ml/min.	Main dimensions: 90x252x254mm Front panel: Graphical display without backlighting Programs: 5 programs for various stages of implantology Irrigation: 100ml/min. Irrigation Tubing can be	none

		Irrigation Tubing can be inserted ergonomically on the unit's side face	inserted on the unit's front face	
	Foot Control	Main dimension: 154x202x210 Features: 4 buttons for pump on/off Forward/reverse Change programs Motor control (on/off and variable) Power supply: wireless via 3xAA batteries	Main dimension: 215x190x40 (without cable) Features: 4 buttons for pump on/off Forward/reverse Change programs Motor control (on/off and variable) Power supply: wired via cable	Yes, the power supply of the new Implantmed is performed via wireless foot control not via cable.
	Motor with cable	Length: 71,65 mm With LED contacts	Length: 75 mm Without LED contacts	Yes, the new motor with LED contacts (EM-19 LC) disposes of better lightning at a lower temperature as the energy transfer is provided via direct voltage supply and not via generator any more. However, this does not raise any additional questions regarding substantial equivalence.
	SI-SQ	<u>W&H SI-SQ:</u> Connection via USB-cable	<u>Osstell ISQ:</u> Stand-alone device	Yes, the Osstell ISQ is already cleared for market (K082523). The W&H SI-SQ has the same intended use, consists of the same materials and is sterilized the same way as the Osstell ISQ. The only differences are the labeling (W&H) and the connection - as the SI-SQ is no stand-alone device. However, this does not raise any additional questions regarding substantial

			equivalence.

Technical data/Functions Implantmed SI-1015			
New Device		**Predicate Device**	**Difference**
Max. mechanical output power	80 W	70 W	Yes[5]
Torque at the motor	6.2 Ncm	5.5 Ncm	Yes[5]
Speed range of motor	200 – 40,000 rpm	200 – 40,000 rpm	None
Supply voltage	100-130 VAC	100-130 VAC	None
Rated current	0.3 – 1.6 A	0.2 – 1.6 A	None
Frequency	50-60 Hz	50-60 Hz	None

[5] The new unit offers a higher maximum level of torque output at the motor: 6.2 Ncm.
It allows in its program 4 to adjust torque values up to 80 Ncm (which are needed for implant systems) – instead of previous maximum of 50 Ncm.
This does not lead to any negative effect regarding substantial equivalence because of the constructive power reserves of the motor (no big difference between 5.5 Ncm – 6.2 Ncm for the motor).

Materials			
Item	**New device**	**Predicate device**	**Difference**
Control unit housing	plastic material	plastic material	None
Tubing outer sheath	Customer specific	Customer specific	None
Motor with cable	Stainless steel	Stainless steel	None
Surgical handpieces	Chromium coated steel and chromium coated brass	Chromium coated steel and chromium coated brass	None

SI-SQ	Stainless steel	Stainless steel	None

Hygiene / Maintenance
Surgical Handpieces (WS-56 L, WS-75 L, S-11 L, WS-91 L, WS-92 L), EM-19, EM-19 LC and SI-SQ

Item	New device	Predicate device	Difference
Lubrication	after max. 30 minutes of use EM-19 LC/ EM-19: No lubrication is needed	after max. 30 minutes of use Motor with cable: No lubrication is needed	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
Disinfection	wiping disinfection using disinfectant cloths	wiping disinfection using disinfectant cloths	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

W&H´s Implantmed SI-1015 represents a redesigned and improved version of the predicate device.
The technical principle is the same as within the predicate device.
The main technological characteristics are the same or, at least, quite similar to those of the comparable product.
The Indications for Use statement for the Implantmed SI-1015 is identical to the predicate device.

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. 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. Electromagnetic Compatibility Test according to IEC 60601-1-2:2007: General requirement for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests Product testing of handpiece function and lifecycle testing were performed per ISO 14457:2012: Dentistry – Handpieces and Motors. The results demonstrate substantial equivalence in this regard. Software validation according to IEC 62304:2006: Medical device software – Part 1: Guidance on the application of ISO 14972 to medical device software Thermal safety according to the standard IEC 62471:2006: Photobiological safety of lamps and lamp systems 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 surgical handpieces K011061 and K080939, 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. For the new wireless foot control (S-NW) software verification/validation of the functions of the foot control was conducted according to IEC 62304:2006. Additionally, EMC testing was performed to evaluate the risk of communication loss according to IEC 60601-1-2:2007 and Electrical Safety Tests have been done according to IEC 60601-1-1:2005.
Clinical Testing	Clinical data were not needed for this new product.
Conclusion	W&H considers the “Implantmed SI-1015 incl. Accessories” 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 establishment 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.