K181110

Section V – 510(k) Summary
for
PROPHYflex 4
Handpiece and Accessories

1. Submitter Information**:**

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2. Device Name:
   - Proprietary Name: PROPHYflex 4
   - Manufacturer: Kaltenbach & Voigt GmbH
   - Common Name: Dental Handpiece
   - Classification Name: Dental Handpiece and Accessories
   - CFR Number: 872.4200
   - Device Class: I
   - Product Code: EFB

3. Predicate Device:
   - Proprietary Name: AIR-FLOW Handy 3.0 Plus (K151912)
   - Manufacturer: E.M.S. Electro Medical Systems S.A.
   - Common Name: Dental Handpiece
   - Classification Name: Dental Handpiece and Accessories
   - CFR Number: 872.4200
   - Device Class: I
   - Product Code: EFB

   Reference Predicate #1:
   - Proprietary Name: AIR-FLOW handy 3.0 PERIO (K132480)
   - Manufacturer: E.M.S. ELECTRO MEDICAL SYSTEMS S.A.
   - Common Name: Dental Handpiece
   - Classification Name: Dental Handpiece and Accessories
   - CFR Number: 872.4200
   - Device Class: I
   - Product Code: EFB

Reference Device #2:

- Proprietary Name: PROPHYflex 2 (K973876)
- Manufacturer: Kaltenbach & Voigt GmbH
- Common Name: Dental Handpiece
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EFB

Reference Device #3:

- Proprietary Name: SMARTmatic (K163239)
- Manufacturer: Kaltenbach & Voigt GmbH
- Common Name: Handpiece, belt and/or gear driven, dental
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EFA

Reference Device #4:

- Proprietary Name: ELECTROmatic (K163317)
- Manufacturer: Kaltenbach & Voigt GmbH
- Common Name: Dental Handpiece
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EBW

4. Description of Device:

The PROPHYflex 4 is an air polishing device/powder jet handpiece that projects a mixture of water and air with sodium bicarbonate, calcium carbonate or fine glycine power onto tooth surfaces. The device includes the handpiece main body with adjustable spray feature, two cannulas, a wrench for installing the cannula, two interchangeable gripping sleeves, powder container with cover, a cleaning burr and nozzle pin, and a set of spare o-rings. An optional adapter and perio tip can be installed for subgingival treatments.

The powder is filled into the powder container by the user. When activated through foot control, air is pushed into the powder container, swirling the powder and pushing it through the device and out of the cannula. The spray is only mixed with the air and powder at the very tip of the cannula, providing an even and gentle cleaning effect. The amount of powder can be regulated via three different spray settings by the adjusting ring, helping the users to perform individual treatments such as subgingival biofilm removal, removal of discoloration and bacterial plaque, orthodontics, cleaning prior to fissure sealing, prosthetics, conservative and aesthetic dentistry by providing the possibility to adjust the cleaning effects to the clinical situation of the patient at hand.

The components of the PROPHYflex 4, including the powder container, is to be completely reprocessed after each use.

The three powder levels are as follows:

- Highest Level: Suitable for supragingival treatment and offers full cleaning power
- Medium Level: Suitable for sub- and supragingival treatment and enables gentle cleaning at a reduced powder quantity
- Lowest Level: Helps rinsing the powder off the tooth and blowing the powder from the system after the treatment

During supragingival treatments (e.g. stain removal), the device doesn't touch the patient but will be placed 3 – 5 mm from the area that is to be cleaned. During subgingival treatments (biofilm management) with the perio tip, the tip is inserted into the pocket up to 5mm and angled towards the tooth.

Per the Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, Kaltenbach and Voigt GmbH is bundling the PROPHYflex 4 Dental Handpiece and Accessories models listed below as the models do not differ significantly in purpose, design, materials, energy source, function or any other feature related to substantial equivalence. The device description and intended use are identical for all models listed below. The differences between the models are coupler adapter and color selection. All critical components within the PROPHYflex 4 Dental Handpiece and Accessories are common.

The PROPHYflex 4 Dental Handpiece and Accessories are available in the following models in table 5.1 below.

Table 5.1

Series	**Model**	**Description**
PROPHYflex 4	3.002.8000	PROPHYflex 4 – Wave color PROPHYflex 4 for use with KaVo MULTIflex coupler
PROPHYflex 4	3.002.8200	PROPHYflex 4 - Lime color PROPHYflex 4 for use with KaVo MULTIflex coupler
PROPHYflex 4	3.002.8800	PROPHYflex 4 – Flamingo color PROPHYflex 4 for use with KaVo MULTIflex coupler
PROPHYflex 4	3.004.5900	PROPHYflex 4 S - Wave color PROPHYflex 4 for use with Sirona coupler
PROPHYflex 4	3.004.5930	PROPHYflex 4 S - Lime color PROPHYflex 4 for use with Sirona coupler
PROPHYflex 4	3.004.5950	PROPHYflex 4 S - Flamingo color PROPHYflex 4 for use with Sirona coupler

Accessories:

Optional accessories (devices) that are integrated/attached to the PROPHYflex 4 Handpiece and Accessories are 510(k) Exempt devices and have been tested as part of the PROPHYflex 4 Handpiece and Accessories Performance Bench Testing (Section 18). Also, Kaltenbach and Voigt GmbH has quality system processes implemented for risk assessment for devices manufactured in compliance with ISO 14971:2007 as referenced in section 9 (Declarations of Conformity and Summary Reports). This includes the PROPHYflex 4 Handpiece and Accessories with attached/integrated Devices / Accessories listed below in Table 5.2.

Table 5.2

Device / Accessory	Device Description	Manufacturer	Product Code	510(k) Clearance
PROPHYflex Powder - Orange	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYflex Powder - Berry	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYflex Powder - Cherry	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYflex Powder - Mint	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYpearls - Neutral	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYpearls - Mint	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYpearls - Peach	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYpearls - Orange	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYpearls – Black Currant	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt
PROPHYflex Perio Powder	Oral cavity abrasive polishing agent	Kaltenbach and Voigt GmbH	EJR	Exempt

Principle of Operation / Mechanism of Action:

PROPHYflex 4 connects to a dental treatment unit's tubing via KaVo MULTIflex coupler or a Sirona coupler that supplies air and water to the handpiece separately. The air is redirected through the PROPHYflex 4 main body to the powder container. The powder container – holding the sodium bicarbonate or calcium carbonate or glycine powder – is filled according to the treatment indication. The air draws the powder from the container to the cannula in the front of the handpiece. There, the powder is mixed with water that has been transported from the dental treatment unit coupling system to the tip of the cannula. The cannula focuses this air, water and powder mixture into a stream. The air and water can be adjusted at the dental treatment unit or via the treatment unit foot control. The powder can be adjusted to 3 different levels using the adjustable ring at the base of the PROPHYflex 4 handpiece.

5. Indications for Use:

The PROPHYflex 4 Handpiece and Accessories is a dental handpiece intended for perform supragingival and subgingival prophylaxis treatments. The prophylaxis treatments are obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the treatment site. PROPHYflex 4 Handpiece and Accessories in supra-gingival configuration is intended for use in the cleaning and polishing of teeth by removal soft deposits and areas of discoloration as well as preparing teeth for fillings or veneers and cleaning fixed bands and brackets on orthodontic appliances. PROPHYflex 4 Handpiece and Accessories in subgingival configuration is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

6. Description of Substantial Equivalence:
Technological Characteristics:

The proposed device (PROPHYflex 4 Handpiece and Accessories) from Kaltenbach & Voigt GmbH function in a manner similar to and are intended for the same indications for use as the predicate device AIR-FLOW Handy 3.0 Plus (K151912) marketed by E.M.S. Electro Medical Systems S.A.. There are numerous similar design, materials, and technological characteristics such as indications for use, Subgingival usage depth to 5mm, principle of operation, air polishing, max mode operation, internal spray, air/water ports, coupling dimensions, transportation and connections (Air pressure and relative humidity), as the ability to connect to KaVo MULTI-flex coupling and Sirona coupling.

In addition, both the proposed device (PROPHYflex 4 Handpiece and Accessories) and the predicate device AIR-FLOW Handy 3.0 Plus (K151912) provide air for dental handpieces by using a connection according to ISO 7785-1, ISO 14457 and ISO 9168 (2009-07-15 - Dentistry - Hose connectors for air driven dental handpieces). Furthermore, both the proposed device and the predicate device complies with conformance standard DIN 19402 (Powder Jet Handpieces) and ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).

However, there are different technological characteristics such as the proposed device has a Middle Mode and a Spray-function Mode (without powder, water only) capability where the predicate device does not. The proposed device is 10 mm shorter and 3 mm thinner than the predicate device and as well as being 5.9 dB quitter than the predicate device. The proposed device operating temperature is 18.0°C – 25.1°C where the predicate is 19.93°C – 23.33°C. The Maximum Air Pressure for the proposed device is 3.2 - 5 bar (46 - 73 psi) where the predicate is 2.7 – 3.5 bar (39 – 51 psi). The Air and water supply for the proposed device is 6.4 – 14.3 Nl/min and the predicate is 10.3 – 13.5 Nl/min. The proposed device Maximum water pressure is 1.0 - 2.5 bar (15 - 36 psi) where the predicate is 1.0 – 2.2 bar (15 – 32 psi). The spray water for the proposed device is 28 – 54 ml/min where the predicate is 106 ml/min.

These different technological characteristics do not raise new concerns of substantial equivalence. The comparison table below (table 5.3) for the PROPHYflex 4 Handpiece and Accessories (proposed device) and the AIR-FLOW Handy 3.0 Plus (K151912) (predicate device) are substantially equivalent in terms of indication for use, technology and performance specifications as the few differences between the proposed device and the predicate device do not impact substantial equivalence. The performance testing results provided in this submission supports that the proposed device performs as well as the predicate devices for its intended use. Hence, the device is deemed to be substantially equivalent to the AIR-FLOW Handy 3.0 Plus (K151912).

Please note, reference device #2 (PROPHYflex 2 and Accessories (K973876)) is references as it has numerous identical features as the Proposed Device (PROPHYflex 4). Reference Device #1 is listed to support the indications for use. Reference devices 3 and 4 (SMARTmatic – K163239 and ELECTROmatic - K163317) are referenced in Biocompatibility section as they contain numerous identical patient contacting materials.

Device Comparison Table:

Table 5.3

Descriptive Information	**Proposed Device** **PROPHYflex 4 and Accessories**	***Predicate Device*** ***AIR-FLOW Handy 3.0 Plus (K151912)***	***Reference Device #2*** ***PROPHYflex 2 and Accessories (K973876)***	***Reference Predicate #1*** ***AIR-FLOW handy 3.0 PERIO (K132480)***
Indications for Use				
Indications for Use	The PROPHYflex 4 Handpiece and Accessories is a dental handpiece intended for perform supragingival and subgingival prophylaxis treatments. The prophylaxis treatments are obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the treatment site. PROPHYflex 4 Handpiece and Accessories in supra-gingival configuration is intended for use in the cleaning and polishing of teeth by removal soft deposits and areas of discoloration as well as preparing teeth for fillings or veneers and cleaning fixed bands and brackets on orthodontic appliances. PROPHYflex 4 Handpiece and Accessories in subgingival configuration is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	The AIR-FLOW handy 3.0 PLUS is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances. The AIR-FLOW handy 3.0 PLUS is intended for patients suffering from periodontal disease. The AIR-FLOW handy 3.0 PLUS is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.	The PROPHYflex 2 dental device is intended for use in removing plaque deposits and stains from teeth by projecting a mixture of water, air, and sodium bicarbonate onto tooth surfaces. The product should not be used on patients on a saltless diet, with a renal deficiency, with a chronic respiratory disease, or with chronic diarrhea.	The AIR-FLOW handy 3.0 PERIO is intended for patients suffering from periodontal disease. The AIR-FLOW handy 3.0 PERIO is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200
Regulation Title	Dental handpiece and accessories	Dental handpiece and accessories	Dental handpiece and accessories	Dental handpiece and accessories

Regulation Class	I	I	I	I
Product Code	EFB	EFB	EFB	EFB
Device Design				
Principles of Operation	The PROPHYflex 4 product is designed to apply a cleansing mixture of air, water and different powders to tooth surface in order to remove plaque and stain. The product consists of a stainless shell handpiece that is attached to an air/water coupling, a powder reservoir and a stainless-steel cannula through which the powder spray is projected onto tooth surface.	The principles of operation of the proposed PLUS hand-held device are identical to the predicates PERIO and STANDARD. Both the proposed and parent devices are handheld devices that connect to a standard turbine connection on a dental operative unit and deliver a mixture of water, air and prophylaxis powder to a treatment site.	The PROPHYflex 2 product is designed to apply a cleansing mixture of air, water and sodium bicarbonate to tooth surface in order to remove plaque and stain. The product consists of a stainless shell handpiece that is attached to an air/water coupling, a sodium bicarbonate reservoir and a stainless-steel cannula through which the sodium bicarbonate spray is projected onto tooth surface.	
Operational Modes	• Max Mode • Middle Mode (reduced mode, less powder) • Spray-function Mode (mode without powder, water only)	Max Mode	Max Mode	
Function	Air Polishing	Air Polishing	Air Polishing	Air Polishing
Air / water ports	Internal Spray	Internal Spray	Internal Spray	
Fiberoptics	N/A	N/A	N/A	
Dimensions	Length (with Nozzle and Grip Sleeve long): Up to 190 mm Height: Up to 84mm Largest diameter: Up to 40mm	Length: Up to 200 mm Height: Up to 110mm (with MULTIflex-coupling) Largest diameter: Up to 43mm	Length (with Nozzle): Up to 263 mm Height: Up to 89mm Largest diameter: Up to 38mm	
Type of chuck	N/A	N/A	N/A	
Coupling Dimensions	Complies with ISO 7785-1, ISO 14457 and ISO 9168.	Complies with ISO 7785-1, ISO 14457 and ISO 9168.	Complies with ISO 7785-1, ISO 14457, and ISO 9168.	
Accessories / Compatible Prophylaxis Powders	PROPHYflex Powder, PROPHYpearls, PROPHYflex Perio Powder	Perio (Glycine)	PROPHYflex Powder, PROPHYpearls, PROPHYflex Perio Powder	
Rotary Instruments	N/A	N/A	N/A	

Composition of Materials				
Direct patient-contacting portions of the device	All materials for the PROPHYflex 4 are listed in the tables below including chemical composition of the waterlines and the patient-contacting portions of the device. Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	
Indirect patient-contacting portions of the device (water / air lines)	All materials for the PROPHYflex 4 are listed in the tables below including chemical composition of the waterlines and the patient-contacting portions of the device. Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	
Technical Specifications				
Chuck Design	N/A	N/A	N/A	
Light Intensity	N/A	N/A	N/A	
Bur Retention Force	N/A	N/A	N/A	
Bur Extraction Force	N/A	N/A	N/A	
Treatment Site	Supragingival and Subgingival	Supragingival and Subgingival	Supragingival	Subgingival
Subgingival usage depth	Up to 5mm	Up to 4mm	N/A	Up to 5mm
Transportation and Storage Condition - Temperature	-20 °C to +70 °C (-4 °F to +158 °F)	Storage: +5°C to +40°C Transportation: -10°C to +40°C (ventilated) or 60°C (non ventilated)	-20 °C to +70 °C (-4 °F to +158 °F)	
Transportation and Storage Condition – Relative Humidity	5% RH to 85% RH absence of condensation	Storage: 5% to 85% relative humidity Transportation: 75% relative humidity	5% RH to 85% RH absence of condensation	

Transportation and Storage Condition – Air Pressure	700 hPa to 1060 hPa (10 psi to 15 psi)	Storage: 500 hPa to 1060 hPa air pressure Transportation: min. 700hPa air pressure	700 hPa to 1060 hPa (10 psi to 15 psi)	
Noise Level	56.6 – 69.0 dB(A)	74.9 dB(A)	71.6 dB(A)	
Temperature Grip Sleeve	18,0°C – 25,1°C	19,93°C – 23,33°C	21,64°C – 23,59°C	
Maximum Air Pressure	3.2 - 5 bar (46 - 73 psi)	2.7 – 3.5 bar (39 – 51 psi)	3.2 - 5 bar (46 - 73 psi)	
Air and water supply	6.4 – 14.3 Nl/min	10,3 – 13,5 Nl/min	10,5 – 17,4 Nl/min	
Maximum Water Pressure	1.0 - 2.5 bar (15 - 36 psi)	1.0 – 2.2 bar (15 – 32 psi)	1.5 - 2.5 bar (22 - 36 psi)	
Air and Water Supply – Spray Water	28 – 54 ml/min	106 ml/min	50 ml/min	
Speed Range (RPM's)	N/A	N/A	N/A	
Conformance Standards (Handpieces and Motors)	DIN EN ISO 20608 (Dentistry - Powder jet handpieces and powders) DIN 19402 (Powder Jet Handpieces)	DIN 19402 (Powder Jet Handpieces)	DIN 19402 (Powder Jet Handpieces)	
Conformance Standards (Shanks)	N/A	N/A	N/A	
Conformance Standards (Coupling Dimensions)	KaVo MULTIflex-Coupling, Sirona Coupling	KaVo MULTIflex-Coupling, Sirona Coupling Midwest 4-hole connection NSK coupling W&H coupling BienAir-coupling	KaVo MULTIflex-Coupling, Sirona Coupling	
Conformance Standards (Hose Connections)	Complies with ISO 7785-1, ISO 14457 and ISO 9168.	Complies with ISO 7785-1, ISO 14457 and ISO 9168.	Complies with ISO 7785-1, ISO 14457, and ISO 9168.	
Sterilization	Sterilisable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device).	Sterilisable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device.)	Sterilisable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device).	

Lubricant				
Lubricant	N/A	N/A	N/A	

Non-Clinical Test Data:

Performance bench testing according to international standards for dental handpieces has been conducted to determine conformance in regards to:

- Biocompatibility has been completed for the applicable components.
- Comparative performance testing of the functions of the integrated accessories as compared to the cleared stand-a-lone device.

Furthermore, the performance of the PROPHYflex 4 Handpiece and Accessories has been verified utilizing the following standards:

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (Including: Amendment 1 (2013)).
- ISO 9168 Third edition 2009-07-15 Dentistry - Hose connectors for air driven dental handpieces.
- ISO 17665-1 First edition 2006-08-15 - Sterilization of health care products - Moist heat - part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- AAMI / ANSI ST79 2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- ISO 20608:2017 - Air driven powder jet handpieces and powders
- AAMI / ANSI / ISO 10993-1:2009/(R)2013 - Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.
- ISO 10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 (3rd ed) 2010-08-01 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-18 First edition 2005-07-01 - Chemical characterization of materials
- ISO 14971 Second Edition 2007-03-01, Medical Devices - Application of risk management to medical devices.
- Guidance for Industry and FDA Staff:2007-05-02 - Dental Handpieces - Premarket Notification [510(k)] Submissions

Hence the PROPHYflex 4 Handpiece and Accessories demonstrates substantial equivalence.

Clinical Performance Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the PROPHYflex 4 Handpiece and Accessories are deemed to be substantially equivalent to the predicate device.