February 28, 2025

W&H Dentalwerk Bürmoos GmbH
Gerhard Weidler
Regulatory Affairs Manager
Ignaz-Glaser-Straße 53
Bürmoos, Salzburg 5111
AUSTRIA

Re: K242179
Trade/Device Name: Synea Fusion Handpieces (Intensiv & Profin)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: February 3, 2025
Received: February 3, 2025

Dear Gerhard Weidler:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242179

Device Name

Synea Fusion Handpieces (Profin & Intensiv)
WG-67 A, WG-67 LT, WG-68 A, WG-69 A, WG-69 LT, WG-69 A Swiss Edition, WG-69 LT Swiss Edition

Indications for Use *(Describe)*

The reciprocating/oscillating contra-angle handpieces are for the following applications:

Preparation, removing protrusions or excess of filling materials and cements, finishing and polishing in the interdental, supragingival and subgingival regions, plaque removal and IPR (interproximal reduction) in orthodontics.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K242179

People have Priority

Submitter	W&H Dentalwerk Bürmoos GmbH Ignaz-Glaser-Strasse 53 A - 5111 Bürmoos Austria Phone: 00436274 / 6236 -0 Fax: 00436274 / 6236 -55
Registration Number	9681479
Contact Person	Mag. Dr. Gerhard Weidler
Date of Preparation	29.01.2025
Trade Name	Synea Fusion Handpieces (Intensiv & Profin)
Device Name	Reciprocating/oscillating handpieces: WG-67 LT, WG-67 A, WG-68 A, WG-69 LT, WG-69 A, WG-69 LT Swiss Edition, WG-69 A Swiss Edition
Classification Name	Dental Handpiece and Accessories
Regulation Number	872.4200
Regulatory class	1
Product Code	EFB
Predicate Devices	Device Name: “A-dec/W&H Synea Profin reciprocating contra-angle handpiece attachments” 510(k) Number: K082827 (Decision Date: January 7th, 2009) Manufacturer: W&H Dentalwerk Bürmoos GmbH
Device Description	W&H´s reciprocating/oscillating handpieces were developed as dental contra-angle handpieces that are powered by either an air motor or an electric micromotor. The internally mounted gearing elements transmit the supplied rotational movement up to the head-side assembly holding the clamped tool and generating its reciprocal movement. Because of being designed for two different manufacturers´ files/tips (tools), the following types have been developed: > the Synea Profin handpieces WG-67 LT and WG-67 A, intended to be provided with tips/files offered by the Swedish company Dentatus AB (Establishment Reg. No. 8030870) and > the Synea Intensiv handpieces WG-68 A, WG-69 LT and WG-69 A (incl. Swiss Edition for WG-69 A and WG-69 LT), intended to be provided with tips/files offered by the Swiss manufacturer Intensiv SA (Establishment Reg. No. 8030958). All these devices´ application is intended in dentistry.
Indications for Use:	The reciprocating/oscillating contra-angle handpieces are for the following applications: Preparation, removing protrusions or excess of filling materials and cements, finishing and polishing in the interdental, supragingival and subgingival regions, plaque removal and IPR (interproximal reduction) in orthodontics.

1 Comparison:

	Predicate Devices	New Devices	Judgment
Device name	**A-dec/W&H Synea** Profin **Reciproc. contra-angle handpiece**	**W&H Synea Fusion** Profin / Intensiv **Reciproc. contra-angle handpiece**	---
Type	WA-67/1.1 LT / WA-67/1.1 A WA-67/0.4 LT / WA-67/0.4 A	WG-67 LT / WG-67 A WG-68 A WG-69 LT / WG-69 A WG-69 LT / WG-69 A Swiss Edition	---
Manufacturer	W&H Dentalwerk Bürmoos GmbH Est. Reg. No.: 9681479	W&H Dentalwerk Bürmoos GmbH Est. Reg. No.: 9681479	identical
marketed by	A-dec Inc.	W&H Dentalwerk Bürmoos GmbH Dentatus AB, Reg. No. 8030870 Intensiv SA, Reg. No. 8030958	---
Regulatory class	Class I	Class I	identical
Regulation no.	872.4200	872.4200	identical
Product Code	EFB	EFB	identical
Use	Rx only	Rx only	identical
510(k) number	K082827	K242179	---
Indications for use	The A-dec/W&H Synea Profin reciprocating contra-angle handpiece attachment is intended for use in removing protrusions or excess of filling materials and cements, preparation, finishing and polishing in the interdental and subgingival regions, stripping, vibrating of inlays using Dentatus tips and root canal preparations using endodontic files.	The reciprocating/oscillating contra-angle handpieces are for the following applications: Preparation, removing protrusions or excess of filling materials and cements, finishing and polishing in the interdental, supragingival and subgingival regions, plaque removal and IPR (interproximal reduction) in orthodontics.	identical
Appearance	WA-67/1.1 XX WA-67/0.4 XX 	WG-67 XX  WG-68 XX WG-69 XX: 	equivalent
Handpiece Dimensions	WA-67/1.1 XX: 94 x Ø 20,2 mm, head 8,2 mm WA-67/0.4 XX:	WG-67 XX: 94 x Ø 20,2 mm, head 8,2 mm	identical
		WG-68 XX: WG-69 XX: 93,4 x Ø 20,2 mm, head 10 mm	equivalent
Drive / motor connection	ISO 3964	ISO 3964	identical
Max drive speed	WA-67/1.1 XX: WA-67/0.4 XX: 20.000 RPM	WG-67 XX: 20.000 RPM	identical
		WG-68 XX: 20.000 RPM	identical
		WG-69 XX: 40.000 RPM	similar *)
Gearing ratio	WA-67/1.1 XX: WA-67/0.4 XX: 2:1	WG-67 XX: 2:1	identical
		WG-68 XX: 1:1	similar *)
		WG-69 XX: 2:1	identical

Files/tips	PROFIN / Dentatus LDT and LTA	WG-67 XX:	Dentatus LTA, EVA, PER-IO-TOR	equivalent
		WG-68 XX:	Intensiv Ortho-Strips System, Intensiv Proxoshape, Intensiv Bevelshape	new **)
		WG-69 XX:		
File stroke	WA-67/1.1 XX: 1,1 mm WA-67/0.4 XX: 0,4 mm	WG-67 XX:	1,1 mm	identical
		WG-68 XX:	0,9 mm	new **)
		WG-69 XX:		
Light	types “LT”: yes / types “A”: no	types “LT”: yes / types “A”: no		identical
Spray	yes	yes		identical
Sterilization	sterilizable in autoclave. Must be cleaned and sterilized prior to first use and after each patient	sterilizable in autoclave. Must be cleaned and sterilized prior to first use and after each patient		identical
Lubrication	before each sterilization or after 30 minutes of use or once a day	before each sterilization or after 30 minutes of use or at least twice daily		identical

*) The differences in the handpiece´s maximum drive speed and gearing ratio are caused by the tip manufacturers´ recommendations.
**) Different manufacturer (Intensiv SA) of files for the new handpieces, but identical clinical applications. Safety and effectiveness of the new handpieces are not affected.

1.1 Summary of Technological Characteristics

The proposed devices are similar in terms of design, operating principles and intended use and have similar technological characteristics as the predicate devices. The materials used on these devices are also used in the legally marketed predicate devices.

2 Applied standards:

Non-clinical testing	Type testing according to ISO 14457:2017 “Dentistry – Handpieces and motors” Biological Assessment / Cytotoxicity Testing according to ISO 10993-1:2009 + Cor 1:2010 “Biological evaluation of medical devices – Part 1: Evaluation and testing” ISO 7405:2008 + A1:2013 “Dentistry – Evaluation of biocompatibility of medical devices used in dentistry” Reprocessing Tests under consideration of ISO 17664:2017 “Reprocessing of Health Care Products - Information to be provided by the manufacturer for the processing of medical devices” ANSI/AAMI ST79:2010 + A1:2010 + A2:2011 + A3:2012 + A4:2013 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” ISO 17665-1:2006 “Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices” Risk Assessment according to ISO 14971:2007. “Medical devices - Application of risk management to medical devices” Additionally, different further tests, such as material tests (reg. chemical resistance), lifetime tests, torque and functionality test and tests for ensuring the stability of packaging were performed house-internally and confirmed the product´s suitability for the use in practice.
Clinical Testing	Clinical performance testing was not conducted.

3 Performance Data:

Non-clinical testing has been performed showing that the device performs as intended and are substantially equivalent to the predicate device (K082827).

3.1 Biocompatibility

An evaluation of biocompatibility according to ISO 10993-1 was performed.

3.2 Re-processing Validation

Reprocessing validation was provided per the FDA Guidance Document for “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”. Cleaning and sterilization validation was performed for the new handpieces.

3.3 Performance Testing

Functional testing of the new handpieces to test the application, settings, and features per the device specifications requirements was performed.

4 Substantial Equivalence Summary / Conclusion:

Based on available 510(k) information provided herein, the Synea Fusion Handpieces (Profin, Intensiv) are considered substantially equivalent to the predicate devices in terms of indications for use, technology and performance specifications.

There are no differences between the devices which may raise new issues concerning safety or effectiveness.