July 15, 2022

Jaintek Co.,Ltd
℅ Dave Yungvirt
Most Responsible Person
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K221814
Trade/Device Name: OK Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: June 16, 2022
Received: June 22, 2022

Dear Dave Yungvirt:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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, M.ChE.
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
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221814

Device Name
Trade Name: OK Handpiece

Indications for Use *(Describe)*
A dental contra-angle handpiece that attaching a vertical reciprocating dental strips intended to be used in interproximal reduction of teeth; And it is part of orthodontic treatment of finishing interdental and subgingival area, finishing cavity edges, removing the dentin of teeth adjacent, removing subgingival plague and tripping. The device incorporates a small micro motor normally driven by compressed air; This is a reusable device.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K221814

1. SUBMITTER INFORMATION

Manufacturer: JAINTECK CO., LTD.

#302, 419, Byeolmang-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea

Contact Person: Jung Gun Lee / Representative

Tel) +82-31-495-9091

Fax) +82-31-495-9092

Email) jain98@naver.com

Date Prepared: May 5, 2022

2. DEVICE INFORMATION

Trade Name: OK Handpiece

Model Number: OKH4

Common Name: Reciprocating Contra Angle Handpiece

Product Code: EFB

Regulation Number: 21 CFR 872.4200

Class: 1

3. PREDICATE DEVICE INFORMATION

Predicate Device: K082827 (A-DEC/W&H PROFIN RECIPROCATING CONTRA-ANGLE HANDPIECE ATTACHMENT, WA-67A)

Reference Device: K150750 (Contra-Angle Handpieces, ENDO 6:1)

4. DESCRIPTION OF THE DEVICE

The OK handpiece is a reciprocating contra-angle handpiece that is used in connection with an air motor. The rotational force of the air motor is transmitted to the handpiece head through the shaft of the handpiece body, and the rotational force of the shaft is converted into vertical reciprocating

motion in the head.
The OK handpiece is a reprocessing medical device. Users must steam sterilize before each use, and clean thoroughly after use.
The OK handpiece does not have water/air spray and light supply. Therefore, the air motor connection of the handpiece is designed to comply with the coupling size of TYPE 1 of ISO 3964.
For the strip connecting to the OK handpiece, you must use Orthok-Strips and OK Proxofile of Jaintek Co., Ltd.

5. INDICATION FOR USE

A dental contra-angle handpiece that attaching a vertical reciprocating dental strips intended to be used in interproximal reduction of teeth; And it is part of orthodontic treatment of finishing interdental and subgingival area, finishing cavity edges, removing the dentin of teeth adjacent, removing subgingival plague and tripping. The device incorporates a small micro motor normally driven by compressed air; This is a reusable device.

6. TECHNICLOGICAL CHARACTERISTICS

	Subject Device	Predicate Device 1	Predicate Device 2	Remark
510(k) Number	TBD	K082827	K150750	-
Proprietary Name	OK Handpiece (Model#: OKH4)	A-DEC/W&H PROFIN RECIPROCATING CONTRA-ANGLE HANDPIECE ATTACHMENT	Contra-Angle Handpieces	-
Model Number	OKH4	WA-67A	ENDO 6:1	-
Manufacturer	JAINTECK CO., LTD.	A-DEC, INC.	Sirona Dental Systems GMBH	-
Regulatory Class	Class I	Class I	Class I	Same
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	Same
Product Code	EFB	EFB	EGS	Same
Indication for Use	A dental contra-angle handpiece that attaching a vertical reciprocating dental endpiece(strips) intended to be used in interproximal reduction of teeth; And it is part of orthodontic	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	The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained	Similar

	treatment of finishing interdental and subgingival area, finishing cavity edges, removing the dentin of teeth adjacent, removing subgingival plague and tripping. The device incorporates a small micro motor normally driven by compressed air; This is a reusable device.	subgingival regions, stripping, vibrating of inlays using Dentatus tips and root canal preparations using endodontic files.	dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.	
Handpiece Type	Contra-angle handpiece	Contra-angle handpiece	Contra-angle handpiece	Same
Movement of connected strips	Vertical reciprocating	Vertical reciprocating	Rotation	Same
Composition of material	Stainless Still	Stainless Still	Stainless Still	Same
Motor Coupling	ISO 3964 Compliance	ISO 3964 Compliance	ISO 3964 Compliance	Same
Air/Water spray	Not applicable	Water spray	Not applicable	Same
Bur Extraction force	22N ≤	Unknown	Unknown	Different
Light (Fiber optics)	Not applicable	Not applicable	Not applicable	Same
Max rotation speed	10,000 rpm	20,000 rpm	40,000 rpm	Different
Type of chuck	Sliding chuck	Sliding chuck	Push Button	Same
Sterilization	Steam sterilization	Steam sterilization	Steam sterilization	Same
Lubricant	PANS SPRAY PLUS (K163483)	Oil F1, MD-400 (K162926)	T1 Spray (K150750)	-

The subject device has the same Indication for use, Operation mode, No fiberoptics, type of chuck, coupling dimensions, conformance with standards for shanks, No hose connection, movement of connected strips, sterilization method, and reuse life as predicate device 1.

Predicate device 1 has a water spray function, but subject device does not have a water spray function. However, since the predicate device 2 also does not have a water spray function, the presence or absence of the water jet function does not affect safety and effectiveness.

Since the bur extraction force of the predicates devices is unknown, it is not possible to compare

them equivalence. But, since the extraction force of the subject device satisfies the requirements of ISO 14457, safety and effectiveness are not affected.

The subject device, predicate device 1, and predicate device 2 have different RPM ranges. However, since the RPM range of the target device is within the RPM range of the preceding device, safety or effectiveness is not affected.

An accurate comparison of the raw materials for human contact between the subject and predicate devices cannot be made due to lack of information. However, since the suitability of the raw material has been verified through biocompatibility evaluation, it does not cause any problems with safety or effectiveness.

7. SUMMARY OF NON-CLINICAL DATA

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was substantially equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

○ Bench Test

The subject device is complied with the following performance standards:

- ISO 3964 Third edition 11-2016, Dentistry - Coupling dimensions for handpiece connectors
- ISO 14457 Second edition 2017-10, Dentistry - Handpieces and motors

○ Biocompatibility

The subject device is manufactured from 304 stainless steel, which has been evaluated for the following biocompatibility in accordance with ISO 10993-1:2018.

- ISO 10993-5:2009 (In vitro Cytotoxicity)
- ISO 10993-10:2010 (Skin Sensitization)
- ISO 10993-10:2010 (Oral mucosa irritation)

○ Sterilization

The subject device is provided non-sterile. The end user must sterilize according to the recommended parameters (Pre-vacuum, 135 degrees/3 minutes sterilization, 30 minutes drying) using an autoclave before use. In this sterilization parameter, the subject device meets Sterility Assurance Level of 1E-6 and has been verified according to the standards below.

- 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
- ISO/TS 17665-2:2009, Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1
- ISO 11138-1:2017, Sterilization of health care products — Biological indicators — Part 1: General requirements
- ISO 11737-1:2018, Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
- ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

10. SUMMARY OF CLINICAL DATA

Clinical Data was not required to demonstrate the substantial equivalence.

11. CONCLUSION

OK Handpiece is manufactured from biocompatible raw materials. In addition, it has the similar indication for use, the same design characteristics, and similar performance as the predicate device. And the substantial equivalence of the subject device was confirmed through a non-clinical testing. Therefore, the OK Handpiece has been proven to be equivalent to a predicate device.