



November 12, 2024

Foshan SOCO Precision Instrument Co.,Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui,
No.5, YiHe North Rd., FangShan District
Beijing, 102401
China

Re: K241074

Trade/Device Name: High-speed Air Turbine Handpieces (SCHG01, SCHG03, SCHG18, SCHF19, SCHF22), Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors (Straight Handpieces: SCHD05-S, SCHD16-S, SCHD17-S, SCHD24-S, SCHD27-S Geared Angle Handpieces: SCHD05-C, SCHD06-C, SCHD16-C, SCHD17-C, SCHD24-C, SCHD27-C, SCHD29-S, SCHB4, SCHB5, SCHB20, SCHB64 Air Motors: SCHD16-M, SCHD17-M, SCHD24-M, SCHD27-M)

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece And Accessories

Regulatory Class: Class I, reserved

Product Code: EFB, EGS

Dated: October 14, 2024

Received: October 15, 2024

Dear Ray Wang:

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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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,



Bobak
Shirmohammadi -S

For Michael E. 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
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K241074

Device Name

High-speed Air Turbine Handpieces (SCHG01, SCHG03, SCHG18, SCHF19, SCHF22);
Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors
(Straight Handpieces:
SCHD05-S, SCHD16-S, SCHD17-S, SCHD24-S, SCHD27-S
Geared Angle Handpieces:
SCHD05-C, SCHD06-C, SCHD16-C, SCHD17-C, SCHD24-C, SCHD27-C, SCHD29-S, SCHB4,
SCHB5, SCHB20, SCHB64
Air Motors:
SCHD16-M, SCHD17-M, SCHD24-M, SCHD27-M)

Indications for Use (Describe)

High-speed Air Turbine Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

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.

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The assigned 510(k) Number: K241074

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 10/14/2024

2. Sponsor Identification

Foshan SOCO Precision Instrument Co.,Ltd.

3-5 FL. Bldg 4, District A and 5 FL. Bldg 3, District A Guangdong New Light Source Industrial Base, Luocun, Shishan Town, Nanhai District, Foshan City, 528226, Guangdong, P.R. China

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3. Designated Submission Correspondent

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Contact Person: Ray Wang

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4. Identification of Proposed Device

Trade Name	Model
High-speed Air Turbine Handpieces	SCHG01, SCHG03, SCHG18, SCHF19, SCHF22
Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors	Straight Handpieces: SCHD05-S, SCHD16-S, SCHD17-S, SCHD24-S, SCHD27-S Geared Angle Handpieces: SCHD05-C, SCHD06-C, SCHD16-C, SCHD17-C, SCHD24-C, SCHD27-C, SCHD29-S,

	SCHB4, SCHB5, SCHB20, SCHB64 Air Motors: SCHD16-M, SCHD17-M, SCHD24-M, SCHD27-M
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Common Name: Handpiece, Air-Powered, Dental

Regulatory Information

Classification Name: Handpiece, Air-Powered, Dental

Classification: I

Product Code: EFB; EGS

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental handpiece and accessories

Regulation Medical Specialty: Dental

Review Panel: Dental

Indication For Use Statement:

High-speed Air Turbine Handpieces:

It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors:

It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

5. Device Description

The proposed device is used to hold rotary instruments such as burs and drills to drive movements to achieve dental operations such as cutting, grinding, and drilling. The working principle of the proposed device is that the current and compressed air arrive at the nose through each control valve of the circuit system and air circuit system to drive the motor, turbine (or blade) rotation (shaft core rotation), thus driving the needle rotation to achieve the purpose of drilling and tooth cutting, and the other water and air meet the head to achieve the cooling purpose through each control valve.

6. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K220179

Product Name: High-Speed Air Turbine Handpieces / Straight Handpieces / Geared Angle Handpieces / Air Motors

Manufacturer: Foshan COXO Medical Instrument Co., Ltd.

7. Non-Clinical Test Conclusion

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:

- ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Pyrogen Study in Rabbits using USP General Chapter <151> Pyrogen Test
- IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 80601-2-60: 2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- ISO 14457: 2017 Dentistry - Handpieces and motors
- ISO 17664: 2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
- 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 9168: 2009 Dentistry - Hose connectors for air driven dental handpieces

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device (K241074)	Predicate Device (K220179)	Remark
Manufacturer	Foshan SOCO Precision Instrument Co.,Ltd.	Foshan COXO Medical Instrument Co., Ltd.	/
Device Name	High-speed Air Turbine Handpieces / Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors	High-Speed Air Turbine Handpieces/ Straight Handpieces/ Geared Angle Handpieces/ Air Motors	/

Model	High-speed Air Turbine Handpieces: SCHG01, SCHG03, SCHG18, SCHF19, SCHF22 Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors: Straight Handpieces: SCHD05-S, SCHD16-S, SCHD17-S, SCHD24-S, SCHD27-S Geared Angle Handpieces: SCHD05-C, SCHD06-C, SCHD16-C, SCHD17-C, SCHD24-C, SCHD27-C, SCHD29-S, SCHB4, SCHB5, SCHB20, SCHB64 Air Motors: SCHD16-M, SCHD17-M, SCHD24-M, SCHD27-M	High-Speed Air Turbine Handpieces: CX207, CX207-G, CX207-2, CX207-A, CX207-A-2, CX207-B, CX207-B-2, CX207-C, CX207-C-2, CX207-W, CX207-W-2 Straight Handpieces: CX235-2, CX235-2A, CX235-2B, CX235-2F, CX235-2G, CX235-2C, CX23 5- 2S2 Geared Angle Handpieces: CX235-1B, CX235-1C, CX235-1F, CX235-1G, CX235C1, CX235C2, CX235C3, CX235C4, CX235C5, CX235C6, CX235C7, CX235C8, CX235-2S, CX235-2S1 Air Motors: CX235-3B, CX235-3F, CX235-3C	Analysis 1
Product Code	EFB, EGS	EFB, EGS	SAME
Regulation No.	21 CFR 872.4200	21 CFR 872.4200	SAME
Class	I	I	SAME
Indication For Use	High-speed Air Turbine Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	High-Speed Air Turbine Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. Straight Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. Geared Angle Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. Air Motors: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	SAME
Air/water ports	4/6 ports	2/4/6 ports	SAME
Fiber optic Glass Rod	SCHB5, SCHD24-S, SCHD24-C	CX207-G, CX235-1C, CX235C7	Analysis 1
Composition of material	Copper (chromium plating), aluminum, rubber and stainless steel	Copper (chromium plating), aluminum, rubber and stainless steel	SAME
Chuck	Push button, Latch, Wrench	Push button, Screw	Analysis 2

Maximum air pressure	High-speed Air Turbine Handpieces: 0.2 ~0.25Mpa Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors: 0.245MPa ~ 0.3925MPa	High-speed Air Turbine Handpieces: 0.2 ~0.25Mpa Straight handpiece & Geared Angle handpiece & Air Motors: 0.245MPa ~ 0.3925MPa	SAME
Maximum water pressure	High-speed Air Turbine Handpieces: 0.2 ~0.25Mpa Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors: 0.245MPa ~ 0.3925MPa	High-Speed Air Turbine Handpieces: 0.2 ~0.25Mpa Straight handpiece & Geared Angle handpiece & Air Motors: 0.245MPa ~ 0.3925MPa	SAME
Speed in rpms	High-speed Air Turbine Handpieces: 280000 ~ 450000rpm Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors: < 40000rpm	High-speed Air Turbine Handpieces: 280000 ~ 450000rpm Straight handpiece & Geared Angle handpiece & Air Motors: < 40000rpm	SAME
Conformance with standards for shanks	Type 3 per ISO 1797-1	Type 3 per ISO 1797-1	SAME
Coupling dimensions	Complied with ISO 3964	Complied with ISO 3964	SAME
Hose connections	Type 2 for 4- hole model Type 3 for 6-hole model	Type 1 for 2-hole model / Type 2 for 4- hole Model / Type 3 for 6-hole model	SAME
Lubricant	The lubricants approved by FDA, such as DO-ALL Dental Handpiece Lubricant (K073353)	The lubricants approved by FDA, such as DO-ALL Dental Handpiece Lubricant (K073353)	SAME
Compliance Standards	Complied with ISO 10993- 5, ISO 10993-10, ISO 10993-11, USP <151> Pyrogen Testing, IEC 60601-1, IEC 60601-1-2, IEC 80601- 2-60, ISO 14457, ISO 17664, ISO 17665-1, ISO 9168	Complied with ISO 10993- 5, ISO 10993-10, ISO 10993-23, ISO 10993-11, USP <151> Pyrogen Testing, IEC 60601-1, IEC 60601-1-2, IEC 80601- 2-60, ISO 14457, ISO 17664, ISO 17665-1, ISO 9168	SAME

Analysis 1

The comparison between the proposed device and each model of the predicate device is shown in Tables 2- Table 5.

Analysis 2

The proposed device is different in Chuck from the predicate device. However, the different not affect the safety and effectiveness of proposed device. Based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

Table 2 Technical comparison for High-speed Air Turbine Handpieces

Item	Proposed Device (K241074) Model: SCHG01	Predicate Device (K220179) Model: CX207	Proposed Device (K241074) Model: SCHG03	Predicate Device (K220179) Model: CX207-W	Proposed Device (K241074) Model: SCHG18	Predicate Device (K220179) Model: CX207-A	Proposed Device (K241074) Model: SCHF19	Predicate Device (K220179) Model: CX207-G	Proposed Device (K241074) Model: SCHF22	Predicate Device (K220179) Model: CX207-W	Remark
Angle	20°	20°	20°	20°	20°	20°	20°	20°	45°	20°	Analysis 3
Cartridge	Collet/Open	Collet/Open	Open	Open	Open	Open	Open	Open	Collet/Open	Open	SAME
Operational modes	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered	SAME
Chuck Type	Push button	Push button	Push button	Push button	Push button	Push button	Push button	Push button	Push button	Push button	SAME
Spray	1 way spray	1 way spray	3 way spray	3 way spray	1 way spray	1 way spray	3 way spray	3 way spray	3way spray	3 way spray	SAME
Hole	4 hole	4 hole	4 hole	4 hole	4 hole	4 hole	6 hole	6 hole	4 hole	4 hole	SAME
LED	/	/	/	/	/	/	LED	LED	LED	/	Analysis 3
LED Voltage	/	/	/	/	/	/	 2.9-3.2V	 2.9-3.2V	/	/	SAME
Light Intensity	/	/	/	/	/	/	>7000 lux	>7000 lux	>7000 lux	/	Analysis 3
Fiber	/	/	/	/	/	/	/	/	/	/	SAME
/											
	Proposed Device (K241074) High-speed Air Turbine Handpieces					Predicate Device (K220179) High-Speed Air Turbine Handpieces					Remark
Grip	Complied with ISO 1797-1					Complied with ISO 1797-1					SAME
Size	Complied with ISO 1797-1					Complied with ISO 1797-1					SAME

Rotation Speed	280000 ~ 450000rpm	280,000 rpm ~ 450,000 rpm	SAME
Coolant Air Supply	> 1.5L/min (at 200kPa)	>1.5 L/min (at 200kPa)	SAME
Coolant Water Supply	>50 mL/min (at 200kPa)	>50 mL/min (at 200kPa)	SAME
Rated Torque	>0.0005N .m	>0.0005N.m (6 hole and 4 hole at 0.28 MPa, 2 hole at 0.22 MPa)	SAME
Air Pressure	0.2~0.25Mpa	0.2 MPa ~ 0.25MPa	SAME
Water Pressure	0.2 MPa ~ 0.25MPa	0.2 MPa ~ 0.25MPa	SAME
Bur extraction force	22N	22N	SAME
Bur type	Shaft diameter: 1.59 to 1.60 mm, Overall length: max. 23 mm, Shaft clamping length: at least 11 mm, Blade diameter: max.2 mm	ISO 1797-1 Type 3, diameter: 1.6mm, fitting length: min. 11mm, overall length: max. 23mm, working diameter: max. 2mm.	SAME
Flow rate	<80 NL/min(at a pressure of (300±100) kpa (3,0±1,0) bar)	<80 NL/min(at a pressure of (300±100) kpa (3,0±1,0) bar)	SAME

Analysis 3

The SCHF22 model of proposed device is different in Angle and LED from the CX207-W model of predicate device. However, based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

Table 3 Technical comparison for Straight Handpieces

Item	Proposed Device (K241074) Model: SCHD05-S	Predicate Device (K220179) Model: CX235-2A	Proposed Device (K241074) Model: SCHD16-S	Predicate Device (K220179) Model: CX235-2F	Proposed Device (K241074) Model: SCHD17-S	Predicate Device (K220179) Model: CX235-2B	Proposed Device (K241074) Model: SCHD24-S	Predicate Device (K220179) Model: CX235-2C	Proposed Device (K241074) Model: SCHD27-S	Predicate Device (K220179) Model: CX235-2G	Remark
Angle	Straight	Straight	Straight	Straight	Straight	Straight	Straight	Straight	Straight	Straight	SAME

Transmission Ratio	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	SAME
Speed	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	< 40000 rpm	SAME
Spray type	External	External	External	External	Inner	Inner	Inner	Inner	Inner	Inner	SAME
Fiber	/	/	/	/	/	/	Glass rod optic	Glass rod optic	/	/	SAME
LED	/	/	/	/	/	/	/	/	/	/	SAME
Light intensity	/	/	/	/	/	/	>7000Lux	>7000Lux	/	/	SAME
Water cooling (ml/min)	/	/	/	/	> 50 (200kPa)	> 50 (200kPa)	/	/	> 50 (200kPa)	> 50 (200kPa)	SAME
Air cooling (L/min)	/	/	/	/	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	SAME
/											
Item	Proposed Device (K241074) Straight Handpieces						Predicate Device (K220179) Straight Handpieces				Remark
Coupling dimensions	Comply with ISO 3964						Comply with ISO 3964				SAME
Bur extraction force	>32 N						>32 N				SAME
Bur type	ISO 1797, type 1, diameter 2.35mm, shaft coupling length: Minimal 11mm, overall length: max 23mm, blade diameter: max 2mm ISO 1797, type 2, diameter 2.35mm, shaft coupling length: Minimal 33mm, overall length: max 50mm, blade diameter: max 2mm.						ISO 1797-1 Type 1, diameter: 2.35mm, fitting length: min.11mm, overall length: max.23mm, working diameter: max.2mm. ISO 1797-1 Type 2, diameter: 2.35mm, fitting length: min.33mm, overall length: max.50mm, working diameter: max.2mm.				SAME

Table 4-1 Technical comparison for Geared Angle Handpieces

Item	Proposed Device (K241074)	Predicate Device (K220179)	Proposed Device (K241074)	Predicate Device (K220179)	Proposed Device (K241074)	Predicate Device (K220179)	Proposed Device (K241074)	Predicate Device (K220179)	Proposed Device (K241074)	Predicate Device (K220179)	Proposed Device (K241074)	Predicate Device (K220179)	Remark
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	Model: SCHD05-C	Model: CX235C1	Model: SCHD06-C	Model: CX235C2	Model: SCHD16-C	Model: CX235-1F	Model: SCHD17-C	Model: CX235-1B	Model: SCHD24-C	Model: CX235-1C	Model: SCHD27-C	Model: CX235-1G	
Angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	SAME
Transmission Ratio	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	SAME
Speed (rpm)	< 20000	< 40000	< 20000	< 40000	< 20000	< 40000	< 20000	< 40000	< 20000	< 40000	< 20000	< 40000	Analysis 4
Spray type	/External	External	External	External	External	External	Inner	Inner	Inner	Inner	Inner	Inner	SAME
Water cooling (ml/min)	/	/	/	/	/	/	> 50 (200kPa)	> 50 (200kPa)	> 50 (200kPa)	> 50 (200kPa)	> 50 (200kPa)	> 50 (200kPa)	SAME
Air cooling (L/min)	/	/	/	/	/	/	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	> 1.5 (200kPa)	SAME
LED	/	/	/	/	/	/	/	/	/	/	/	/	SAME
Fiber	/	/	/	/	/	/	/	/	Glass rod optic	Glass rod optic	/	/	SAME

Table 4-2 Technical comparison for Geared Angle Handpieces

Item	Proposed Device (K241074) Model: SCHD29-S	Predicate Device (K220179) Model: CX235-2S	Proposed Device (K241074) Model: SCHB4	Predicate Device (K220179) Model: CX235C3	Proposed Device (K241074) Model: SCHB5	Predicate Device (K220179) Model: CX235C7	Proposed Device (K241074) Model: SCHB20	Predicate Device (K220179) Model: CX235C6	Proposed Device (K241074) Model: SCHB64	Predicate Device (K220179) Model: CX235C8	Remark
Angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	Contra angle	SAME

Transmission Ratio	1:1	1:1	4:1	4:1	1:5	1:5	20:1	20:1	64:1	64:1	SAME
Speed (rpm)	< 20000	< 40000	< 5000	< 10000	< 100000	< 200000	< 1000	< 2000	< 313	< 625	Analysis 4
Spray type	External	External	External	External	Inner	Inner	External	External	External	External	SAME
Water cooling (ml/min)	> 50 (200kPa)	> 50 (200kPa)	/	/	> 50 (200kPa)	> 50 (200kPa)	> 50 (200kPa)	> 50 (200kPa)	/	/	SAME
Air cooling (L/min)	> 1.5 (200kPa)	> 1.5 (200kPa)	/	/	> 1.5 (200kPa)	> 1.5 (200kPa)	/	/	/	/	SAME
LED	/	/	/	/	/	/	/	/	/	/	SAME
Fiber	/	/	/	/	Glass rod optic	Glass rod optic	/	/	/	/	SAME

Analysis 4

The proposed device is different in Speed from the predicate device. However, we tested as ISO 14457 and based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

Table 4-3 Technical comparison for Geared Angle Handpieces

Item	Proposed Device (K241074) Geared Angle Handpieces	Predicate Device (K220179) Geared Angle Handpieces	Remark
Coupling dimensions	Comply with ISO 3964	Comply with ISO 3964	SAME
Bur extraction force	>32 N	>32 N	SAME
Bur type	ISO 1797, type 1, diameter 2.35mm, shaft coupling length: Minimal 11mm, overall length: max 23mm, blade diameter: max 2mm. ISO 1797, type 2, diameter 2.35mm, shaft coupling length: Minimal 33mm, overall length: max 50mm, blade diameter: max 2mm.	ISO 1797, type 1, diameter 2.35mm, shaft coupling length: Minimal 11mm, overall length: max 23mm, blade diameter: max 2mm. ISO 1797, type 2, diameter 2.35mm, shaft coupling length: Minimal 33mm, overall length: max 50mm, blade diameter: max 2mm.	SAME

	ISO 1797, type 3, diameter1.6mm, shaft cmalping length: Minimal 11mm, overall length: max 23mm, blade diameter: max 2mm.	ISO 1797, type 3, diameter1.6mm, shaft cmalping length: Minimal 11mm, overall length: max 23mm, blade diameter: max 2mm.	
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Table 5 Technical comparison for Air Motors

Item	Proposed Device (K241074) Model: SCHD16-M	Predicate Device (K220179) Model: CX235-3F	Proposed Device (K241074) Model: SCHD17-M	Predicate Device (K220179) Model: CX235-3B	Proposed Device (K241074) Model: SCHD24-M	Predicate Device (K220179) Model: CX235-3C	Proposed Device (K241074) Model: SCHD27-M	Predicate Device (K220179) Model: CX235-3B	Remark
Spray type	External	External	Inner	Inner	Inner	Inner	Inner	Inner	SAME
Connector	4 hole	4 hole or 2 hole	4 hole	4 hole or 2 hole	6 hole	6 hole	4 hole	4 hole or 2 hole	SAME
LED	/	/	/	/	LED (3.3±0.1V)	LED (3.3±0.1V)	/	/	SAME
Light intensity	/	/	/	/	> 7000Lux	> 7000Lux	/	/	SAME
Fiber	/	/	/	/	/	/	/	/	SAME
/									
Item	Proposed Device (K241074) Air Motors				Predicate Device (K220179) Air Motors				Remark
Rotation speed	Forward: 20000 Reverse20000(pm/min at 250 kPa)				12000-20000rpm at 250 kPa				SAME
Cooling water flow	>50 ml/min at 250 kPa				>50 ml/min at 250 kPa				SAME

Spray air source	>1.5 L/min at 250 kPa	>1.5 L/min at 250 kPa	SAME
Coupling dimensions	Comply with ISO 3964	Comply with ISO 3964	SAME

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (K220179).