November 13, 2024

Guangdong JINME Medical Technology Co., Ltd.
℅ Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District, Guangzhou
Guangdong,
CHINA

Re: K240337
Trade/Device Name: Dental Handpiece (Model: J6-126, J6-136, SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB, EGS
Dated: October 8, 2024
Received: October 15, 2024

Dear Cassie Lee:

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 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

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)*

K240337

Device Name

Dental Handpiece (Model: J6-126, J6-136, SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L)

Indications for Use *(Describe)*

For Model J6-126, J6-136:
The Dental Handpiece is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

For Model SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L:
The Dental Handpiece is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.

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 of K240337

This 510(k) summary is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: 2024-11-13

2. Submitter's Information

Company Name: Guangdong JINME Medical Technology Co., Ltd.
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Application Correspondent

Contact Person: Ms. Cassie Lee
Company: Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Title: Manager
Tel: +86 2082662446
Email: regulatory@glomed-info.com

3. Subject Device Information

Company Name: Guangdong JINME Medical Technology Co., Ltd.
Trade/Device Name: Dental Handpiece (Model: J6-126, J6-136, SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L)
Common Name: Handpiece, Contra- And Right-Angle Attachment, Dental (EGS), Handpiece, Air-Powered Dental (EFB)
Classification Name: Dental handpiece and accessories
Primary Product Code: EFB
Secondary Product Code: EGS
Regulation Number: 21 CFR 872.4200
Review Panel: Dental
Regulatory Class: I

4. Predicate Device Information

Predicate Device:
510(k) Number: K182999
Company Name: Nakanishi Inc.
Trade/Device Name: General Cutting Contra Handpiece

Common Name: Handpiece, Contra- And Right-Angle Attachment, Dental
Classification Name: Dental Handpiece And Accessories
Product Code: EGS
Regulation Number: 21 CFR 872.4200
Regulatory Class: I

Reference Device 1:
510(k) Number: K170229
Company Name: Guangdong JINME Medical Technology Co., Ltd.
Trade/Device Name: Dental High-speed Turbine Handpiece
Model: T, S, TU, SU, TP, SP, TUQ, TUP, SUP, SUQ, TUQP, SUQP
Common Name: Handpiece, Air-Powered, Dental
Classification Name: Dental Handpiece And Accessories
Product Code: EFB
Regulation Number: 21 CFR 872.4200
Regulatory Class: I

Reference Device 2:
510(k) Number: K171155
Company Name: NAKANISHI INC.
Trade/Device Name: Surgical Angle Handpiece, Surgical Straight Handpiece
Common Name: Handpiece, Rotary Bone Cutting
Classification Name: Dental Handpiece And Accessories
Product Code: KMW, EGS
Regulation Number: 21 CFR 872.4200
Regulatory Class: I

5. Device Description

The Dental Handpiece is mainly composed of a machine head, handle, transmission shaft, and cartridge, and is designed to be attached to the drive via standard coupling which complies with ISO 3964 and hose connector which complies with ISO 9168. The head clamp accepts an instrument complying with ISO 1797-1. The handpieces are intended to be powered by air-powered or electric-powered, and they are also intended to provide optic and non-optic series. They are intended to be provided non-sterile, so they must be sterilized prior to first use and sterilized after each subsequent use using steam sterilization (moist heat sterilization).

6. Indications for Use

For Model J6-126, J6-136:
The Dental Handpiece is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

For Model SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L:
The Dental Handpiece is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.

7. Comparison to predicate devices

Compared with the predicate devices, the subject device is very similar in technical design, intended use/indications for use, functions, etc. And the differences between the subject device and predicate devices do not raise new questions of safety or effectiveness. Please refer to the detailed Substantial Equivalence Comparison of the subject device and predicate devices in the following table.

Elements of Comparison	Subject Device	Predicate Device (K182999)	Reference Device 1 (K170229)	Reference Device 2 (K171155)	Remark
Company	Guangdong JINME Medical Technology Co., Ltd.	Nakanishi Inc.	Guangdong JINME Medical Technology Co., Ltd.	NAKANISHI INC.	--
Device Name	Dental Handpiece	General Cutting Contra Handpiece	Dental High-speed Turbine Handpiece	Surgical Straight/Angle Handpiece	--
510(k) Number	K240337	K182999	K170229	K171155	--
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	Same
Product Code	EFB, EGS	EGS	EFB	KMW, EGS	Same
Class	I	I	I	I	Same
Intended Use / Indications for Use	For Model J6-126, J6-136: The Dental Handpiece is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. For Model SH11W2, SH11W3, W401LW, W15LW,	The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling	Dental High-speed Turbine Handpiece is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	The Surgical Straight/Angle Handpiece Series is intended for use by licensed professionals for oral surgical and dental use. Typical uses include sectioning and removal of wisdom teeth, cutting teeth, oral surgery (such as root tip resection, bone removal, bone shaping) and implant treatment (such as drilling the	Same as Predicate device and Reference device 1

Elements of Comparison	Subject Device	Predicate Device (K182999)	Reference Device 1 (K170229)	Reference Device 2 (K171155)	Remark
	W142LW, W11L: The Dental Handpiece is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.	materials and removal of crowns and filling materials.		maxilla and mandible).	
Device Design					
Operational Modes	Electronical-powered or Air-powered	Electronical-powered or Air-powered	Air-powered	Electronical-powered or Air-powered	Same as predicate device
Water Spray	Yes	Yes	Yes	Yes	Same
Fiberoptics	For model J6-136, J6-126: No, LED For model W15LW, W142LW, W11L, W401LW: Yes, Fiberoptics For SH11W2, SH11W3: No	Optic and non-optic	/	Non-optic	Similar Note 1
Dimensions	J6-126: φ12.5*136 J6-136: φ12.5*101 SH11W2: φ19.7*101 SH11W3:	No publicly available	T: φ12.5*133 S: φ11.2*125 TU: φ12.5*125.7 SU: φ11.2*124.5 TP: φ12.5*126 SP: φ11.2*134 TUQ: φ12.5*127	Overall length varies between 108.7mm~135mm	Different Note 2

Elements of Comparison	Subject Device	Predicate Device (K182999)	Reference Device 1 (K170229)	Reference Device 2 (K171155)	Remark
	φ19.3*133 W401LW: φ13.68*97.7 W15LW: φ9.5*96 W142LW: φ9.5*88 W11LW: φ9.9*97.8		TUP: φ12.5*135 SUP: φ11.2*131 SUQ: φ11.2*127 TUQP: φ12.5*127 SUQP: φ11.2*127		
Type of Chunk	Gland chuck, Mechanical chuck	No publicly available	Push button, Screw	Gland chuck (Bur Lock Ring Chuck)	Different Note 3
Coupling and connector dimensions	For model J6-136, J6-126: ISO 9168 Type 3 For model SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L: ISO 3964 Standard Coupling	ISO 3964 Standard Coupling	ISO 9168 Type 1, Type 2, Type 3	ISO 3964 Standard Coupling	Same
Accessories	Wrench, Oil Injection Quick coupling	No publicly available	/	No publicly available	Different Note 4
Composition of Main Materials	1) Head of handpiece (Stainless Steel, Brass, Titanium) 2) Back cover of Head (Stainless steel) 3) Water path (Stainless steel) 4) Air path (Stainless	No publicly available	Stainless Steel, Brass, Titanium	Stainless Steel, Aluminum	Same with reference device 2

Elements of Comparison	Subject Device	Predicate Device (K182999)	Reference Device 1 (K170229)	Reference Device 2 (K171155)	Remark
	steel)				
Technical Specifications					
Light intensity	⩾7000 lx	No publicly available	⩾7000 lx	No publicly available	Same with reference device 2
Bur Extraction Force	For model J6-126, J6-136, W15LW, W142LW: ⩾22N For model SH11W2, SH11W3, W401LW, W11L: ⩾45N	No publicly available	28N	No publicly available	Similar Note 5
Maximum air pressure	For model J6-126, J6-136, W11L only: 300kPa	No publicly available	177KPa ~ 301KPa	No publicly available	Similar Note 6
Maximum water pressure	For model W401LW, W142LW, W15LW, W11L, J6-126, J6-136 only: 200kPa	No publicly available	For Model T, TU, TP, TUQ, TUP, TUQP: 0.3 MPa; For Model S, SU, SP, SUP, SUQ, SUQP: 0.25 MPa;	No publicly available	Similar Note 7
Rotation Speed	For model J6-126, J6-136: 300,000rpm ~ 340,000rpm For model SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L: Max Rotation Speed of compatible motors: max.	Max. 40,000 rpm	300,000rpm ~ 400,000rpm	Max Rotation Speed of compatible motors: max. 40,000 rpm	Similar Note 8

Elements of Comparison	Subject Device	Predicate Device (K182999)	Reference Device 1 (K170229)	Reference Device 2 (K171155)	Remark
	40,000 rpm				
Gear Ratio Max rotation speed	For model J6-126, J6-136: Not applicable For model SH11W2, SH11W3, W401LW, W15LW, W142LW, W11L: 1:1 Direct Drive 1:4.2 Increasing 1:5 Increasing 40:1 Reduction	1:1 Direct Drive 1:5 Increasing 16:1 Reduction 10:1 Reduction 4:1 Reduction	Not applicable	1:1 Direct Drive 1:2 Increasing	Similar Note 9
Shank	ISO 1797-1 (Type 1) ISO 1797-1 (Type 2) ISO 1797-1 (Type 3)	ISO 1797-1 (Type 1) ISO 1797-1 (Type 3)	ISO 1797-1 (Type 3)	ISO 1797-1 (Type 2)	Similar Note 10
Lubricants	NSK PANA SPRAY Plus (K163483)	NSK PANA SPRAY Plus (K163483)	NSK PANA SPRAY Plus (K163483)	No publicly available	Same
Sterilization Method	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)	Same
Sterilization Standard	ISO 17665-1	ANSI/AAMI/ISO 17665-1	ISO 17665-1	ISO 17665-1	Same
Performance and Safety	ISO 14457	ISO 14457	ISO 14457	ISO 14457	Same
Biocompatibility Safety	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

Note 1: Although there are differences in fiberoptics, the handpiece with the light have been tested according to ISO 14457 performance requirements. The test results demonstrate that the illuminance of the handpiece light meets ISO 14457 standard's requirements. So, this difference between the subject

and predicate devices does not raise new safety and effectiveness questions.

Note 2: Although the "Head Dimensions" of the subject device is different from the predicate devices, the dimensions are similar to predicate devices. Safety and performance tests were conducted according to IEC 60601 series standards, ISO 14457, ISO 17665, and ISO 10993 series standards, the results demonstrate that the subject device complies with the ISO standards' requirements. So, the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

Note 3: Although the "Type of Chuck" of the subject device is different from the predicate devices, the extraction force of the bur chucked should be designed with the ISO 14457 requirements and the extraction force of the bur of the subject device has been tested according to ISO 14457, the results demonstrate that the subject device complies with the standards' requirements. So, the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

Note 4: Although the "Accessories" of the subject device is different from the predicate devices because the information on accessories of predicate devices is not published. The accessories provided with the subject device include a wrench for assembling and un-assembling and an Oil Injection Quick coupling for maintenance which are common accessories for dental handpieces. These accessories will not affect the product's safety and performance, so, the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

Note 5: Although the "Bur Extraction Force" of the subject device is slightly different from the predicate devices, both the force of the subject device and the predicate devices confirm with ISO 14457 requirements, and the "Bur Extraction Force" of the subject device has been tested according to ISO 14457, the results demonstrate that the subject device is in compliance with the standards' requirements. So, the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

Note 6: Although the "Maximum air pressure" of the subject device is slightly different from the predicate devices, the "Maximum air pressure" of the subject device similar to the reference device K170229 and can be fully covered by the predicate device K170229. The maximum air pressure conforms with ISO 14457 requirements, the results of the subject device demonstrate that the subject device is in compliance with the standards' requirements. So, the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

Note 7: Although the "Maximum water pressure" of the subject device is slightly different from the predicate devices because the Max. water pressure information of predicate devices is not published. The "Maximum water pressure" of our subject device is very common water pressure recommended by legally marketed devices. The Maximum water pressure confirms with ISO 14457 requirements. So, the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

Note 8: The Rotation Speed of the handpiece J6-1126 and J6-136 is close to the predicate device K170299, and the speed of J6-1126 and J6-136 can be fully covered by the reference device K170229.

Besides, the recommended motor speed for the other models except J6-126 and J6-136 is the same as the predicate device K182999. The Rotation Speed of the subject device confirms with ISO 14457 requirements, so the difference between the subject and predicate devices does not raise new safety and effectiveness questions

Note 9: Although the "Gear Ratio Max rotation speed (handpiece)" of the subject device is slightly different from the predicate device K182999, the "Gear Ratio Max rotation speed (handpiece)" of the subject device is very similar to the predicate device, and both of them have the same recommended motor speed. Besides, there is also a wide range of gear ratios for this kind of device, such as the reference device K171436, which has a wider Gear Ratio of 20:1, 16:1, 64:1, 32:1, and 1:1. Furthermore, the max. rotation speed (handpiece) of the subject device confirms with ISO 14457, so the difference between the subject and predicate devices does not raise new safety and effectiveness questions

Note 10: The "Shank" type design of the subject device are the same as the predicate device and reference device, and all of them are designed in common use type according to ISO 1797-1 requirements. The bur extraction force also should be tested according to ISO 14457, the results demonstrated that the extraction force for all kinds of the shank applicable can meet the ISO 14457 standards' requirements, so the difference between the subject and predicate devices does not raise new safety and effectiveness questions.

8. Test Summary

8.1 Summary of Non-clinical tests

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following standards and FDA Guidance document:

- Electrical safety test according to IEC 60601-1, IEC 80601-2-60 and IEC 62417 standard;
- Electromagnetic compatibility test according to IEC 60601-1-2 and IEC/TR 60061-4-2 standard;
- FDA Guidance document, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling;
- FDA Guidance document, Dental Handpieces - Premarket Notification [510(k)] Submissions
- Biocompatibility safety test according to ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-23;
- Performance test according to ISO 14457;
- Validation of the effectiveness of reprocessing and validation of the maximum number of reprocessing cycles according to ISO 17665-1;

8.2 Summary of Clinical Testing

Clinical testing was not included in the submission..

9. Final conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the predicate devices.