November 21, 2023

Guilin Refine Medical Instrument Co., Ltd.
℅ Alice Yang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
CHINA

Re: K230641
Trade/Device Name: Ultrasonic Scaler Tips
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: August 28, 2023
Received: August 28, 2023

Dear Alice Yang:

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.

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
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Respiratory, ENT and Dental Devices
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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)*
K230641

Device Name

Ultrasonic Scaler Tips

Indications for Use *(Describe)*

The ultrasonic scaler tips are intended for use by dental professionals to:
1. Remove supra and sub gingival calculus deposits and stain from the teeth;
2. Clean and irrigate root canals.

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
K230641

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: November 20, 2023

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Ultrasonic Scaler Tips
Model	GD1, GD2, GD4, GD5, GD6, PD1, PD3, PD4, PD4D, ED1
Regulatory Class	Class II
Classification	21 CFR 872.4850 / Ultrasonic scaler / ELC
Submission type	Traditional 510(K)

4. Predicate Device

1. Sapphire Plus@ Tips, San Diego Swiss Machining, K960889 (Primary)
2. tün® ultrasonic tips product family, Engineered Endodontics., K182145 (Reference)
3. Symmetry S-Series Piezoelectric Scaling Tips, Hu-Friedy Manufacturing Company, Incorporated, K053178 (Reference).

5. Device Description

Ultrasonic scaler tips are an accessory to a piezoelectric ultrasonic handpiece and scaler unit. The devices are used during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of ultrasonic vibration and in various endodontic applications to prepare the teeth and/or root of the teeth for repair.

The models are GD1, GD2, GD4, GD5, GD6, PD1, PD3, PD4, PD4D, ED1. The Ultrasonic scaler tips are

made from Stainless Steel 30Cr13 and the endo files are made of Nickel Titanium Alloy. The tips will beavailable in M3x0.6 internal thread .

GD series and PD series(except for PD4D) are used to remove calculus deposits from teeth; PD4D and ED1 are used for root canal indication.

6. Intended use & Indication for use

The ultrasonic scaler tips are intended for use by dental professionals to:

1. Remove supra and sub gingival calculus deposits and stain from the teeth;

2. Clean and irrigate root canals.

7. Comparison to the Predicate Device

Features	**Proposed device Ultrasonic Scaler Tip**	**Primary Predicate device K960889 Sapphire Plus@ Tips**	**Reference Predicate device K053178 Symmetry S-Series Piezoelectric Scaling Tips**	**Reference Predicate device K182145 tün® ultrasonic tips Product Family**	**comment**
Product code	ELC	ELC	ELC	ELC	Same
Regulation number	21 CFR 872.4850	21 CFR 872.4850	21 CFR 872.4850	21 CFR 872.4850	Same
Regulation Class	Class II	Class II	Class II	Class II	Same
Regulation Description	Scaler, Ultrasonic	Scaler, Ultrasonic	Scaler, Ultrasonic	Scaler, Ultrasonic	Same
Intended Use	The ultrasonic scaler tips are intended for use by dental professionals to: 1. Remove supra and sub gingival calculus deposits and stain from the teeth;	Reconstructive dental tissue during endo root procedures, crown prep, canal prep. Remove perio prep, root prep	To be used by Dental Professionals during dental cleaning and periodontal (gum) therapy to remove calculus, plaque and staining of the teeth by	tün® ultrasonic tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts	SE

Features	Proposed device Ultrasonic Scaler Tip	Primary Predicate device K960889 Sapphire Plus@ Tips	Reference Predicate device K053178 Symmetry S-Series Piezoelectric Scaling Tips	Reference Predicate device K182145 tün® ultrasonic tips Product Family	comment
	2. Clean and irrigate root canals.		application of an ultrasonic vibrating tip to the teeth.	and other intra-canal blockages.	
Device Description	The device is used during dental cleaning and periodontal(gum) therapy to remove calculus deposits from teeth by application of ultrasonic vibration and in various endodontic applications to prepare the teeth and /or root of the teeth for repair.	The device is used during dental cleaning and periodontal(gum) therapy to remove calculus deposits from teeth by application of ultrasonic vibration and in various endodontic applications to prepare the tooth and /or root of the tooth for repair.	This device is intended to be used by dental professionals for dental cleaning and periodontal therapy to remove calculus from the teeth	tün® ultrasonic tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages.	SE
Operating Principle	The tips are used on piezo ultrasonic endodontic and scaler units which operate in the range of 23kHz-	Used in conjunction with piezoelectric ultrasonic handpiece and scaler.	Compatible with 27-32 kHz generator	tün tips interact with piezo ultrasonic hand piece and unit. tün tips are an accessory to a piezo ultrasonic	Different

Features	Proposed device Ultrasonic Scaler Tip	Primary Predicate device K960889 Sapphire Plus@ Tips	Reference Predicate device K053178 Symmetry S-Series Piezoelectric Scaling Tips	Reference Predicate device K182145 tün® ultrasonic tips Product Family	comment
	33kHz.	Ultrasonic energy vibrates tip at high frequencies (up to 40,000 Hz)		hand piece and unit. tün tips are used on piezo ultrasonic endodontic and scaler units which operate in the range of 20,000hz – 35,000hz.	
Tip Shapes/Types	GD series and PD series(except for PD4D) are used to remove calculus deposits from teeth; PD4D and ED1 are used for root canal indication.	Four different types of tips will be manufactured as follows: Scaler tips, Plugger Tips, Cutting Tips, Spreader Tips	-	1 tip design is devised for post removal; the remaining 5 tips are designed for negotiating the various angles and directions of root canals.	Different
Composition	Stainless Steel 30Cr13 Nickel Titanium Alloy(endo files)	13-8 stainless steel	-	17-4ph Stainless Steel	Different
Coatings	None	Titanium Nitride Zirconium Nitride	-	Nickel Plating or Diamond Nickel Plating	Different
Interaction with other products and/or items used with the product	brands of Piezo-Electric type dental ultrasonic Scalers that use an M3x0.6 thread	-	-	brands of Piezo-Electric type dental ultrasonic Scalers that use an M3x0.5 or M3x0.6 thread	Same

Features	Proposed device Ultrasonic Scaler Tip	Primary Predicate device K960889 Sapphire Plus@ Tips	Reference Predicate device K053178 Symmetry S-Series Piezoelectric Scaling Tips	Reference Predicate device K182145 tün® ultrasonic tips Product Family	comment
Sterilization Status	Provided non-sterile.	Provided non-sterile.	Provided non-sterile.	Provided non-sterile.	Same
Sterilization method	steam sterilization Sterilization requirements: 4 minutes at 132 ℃ a drying time of minimum 20 minutes	Yes, no detail information	Steam sterilize for at least 4 minutes at 270 °F / 132 °C or 30 minutes at 250 °F / 121 °C. Do not heat above 275 °F / 135 °C Recommend at least 30 minute dry time after sterilization cycle	Gravity Steam Sterilizer: • Temperature: 250°F /121°C. • Cycle Time: 30 minutes • Maximum Dry Time: 30 minutes Prevacuum Steam Sterilizer: • Temperature: 270°F /132°C. • Cycle Time: 4 minutes • Maximum Dry Time: 30 minutes	Different
Mechanism of treatment	Application of an ultrasonic vibrating scaler tip to the teeth	Application of an ultrasonic vibrating scaler tip to the teeth	Application of an ultrasonic vibrating scaler tip to the teeth	Application of an ultrasonic vibrating scaler tip to the teeth	Same

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Ultrasonic Scaler Tips was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

process". The biocompatibility testing included the following tests:

- Cytoxicity
- Skin Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-mediated Pyrogens

Reprocessing Validation

Sterilization has been validated in conformance to the FDA recognized consensus standard 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. Cleaning validation testing is performed in accordance with recommended evaluations as listed in AAMI TIR30, AAMI TIR12, and Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings.

Bench Performance Testing

Testing was conducted to demonstrate conformity to the applicable clauses of the following standards:

- ISO 18397 Dentistry Powered scaler
- ISO 3630-5 Dentistry Endodontic instruments Part 5: Shaping and cleaning instruments

Clinical data

The subject of this premarket submission, ultrasonic scaler tips, did not require clinical studies to support substantial equivalence.

9. Conclusion

Based on the similarities in intended use, principles of operation, design rationale, test results, and performance, the subject ultrasonic scaler tips are considered to be substantially equivalent to the predicate devices.