April 30, 2024

Litu Tech Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co. Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K233122
Trade/Device Name: High Speed Air Turbine Handpiece
(G100,G200,G300,G400,G450,G500,G600,G700,G700L,G800,G800L)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: March 29, 2024
Received: March 29, 2024

Dear Diana Hong:

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 Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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.

Submission Number *(if known)*

K233122

Device Name

High Speed Air Turbine Handpiece
(G100,G200,G300,G400,G450,G500,G600,G700,G700L,G800,G800L)

Indications for Use *(Describe)*

High Speed Air 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.

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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K233122

510(k) Summary

Prepared on: 2023-09-27

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Diana Hong
Correspondent Contact Email	info@mid-link.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	High Speed Air Turbine Handpiece (G100,G200,G300,G400,G450,G500,G600,G700,G700L,G800,G800L)
Common Name	Dental handpiece and accessories
Classification Name	Handpiece, Air-Powered, Dental
Regulation Number	872.4200
Product Code	EFB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152146	High Speed Handpieces and Accessories	EFB

Device Description Summary

21 CFR 807.92(a)(4)

The proposed devices, High Speed Air Turbine Handpiece, is a dental abrasive device that rotates at high speed and uses compressed air as the driving force. It has 11 models: G100, G200, G300, G400, G450, G500, G600, G700, G700L, G800 and G800L.

The proposed device has the following features

The cooling system includes air/water spray or only water spray. .

The head types include standard head and miniature head.

The angle of the head and shaft include 45°C and 90°. In general, dentist usually uses 90°handpiece having teeth treatment. Except for wisdom teeth 45°handpieces is considered more desirable for wisdom teeth operation .It is because the 45° angle is more appropriate for the angle of eruption of wisdom teeth.

High Speed Handpieces are able to run from 320,000rmp to 430,000rmp.
G450, G700L and G800L have optic light guide for light function, other models don't have the optic light guide.
Coupling is the accessory for the some models of the proposed handpiece to connect with tubes of dental unit. G500 and G600 require additional 4-hole coupling, and the 4-hole coupling is included in the product package. G450,G700, G700L, G800 and G800L require additional quick coupling, but the quick coupling is not included in the product package. The user shall purchase the compatible coupler for G450,G700, G700L, G800 and G800L.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

High Speed Air 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed device and predicate device have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device and predicate device have the same principles of operation, type of chuck, head angle. Both they have cooling system, and some models of them have the fiber optics. Regarding the technological characteristics, there are difference on Light intensity, Speed in rpms and Bur retention force, but considering the performance test has conducted on the proposed device based on ISO 14457:2017, and the test result demonstrated that the proposed device complies with the standard requirements, the differences on technological characteristics do not affect the safety and effectiveness of the proposed device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The proposed device, High Speed Air Turbine Handpiece, is tested per tISO 14457-2017 Dentistry - Handpieces and motors, to evaluate the handpiece's following particular performance.
Noise level @ Background noise level 56 dB(A)
Flow rate of air supply @ 400kPa
Flow rate of spray air @ 200kPa(2.0 bar)
Flow rate of water supply @200kPa(2.0 bar)
The force required to extract the test mandrels from the chuck system for Type 5 test mandrels
Torque @ Type 5 test mandrels
Speed of handpiece @0.22MPa
Dynamic eccentricity
Stall torque
The light at the output side of the handpiece

The clinical testing is not applicable.

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device K152146.