



September 15, 2025

Premium Plus (Dongguan) Limited
Jessica Mao
Regulatory Affairs Manager
Flat 101, No.122, Tianqiao Road, Changping
Dongguan, Guangdong 523581
CHINA

Re: K251869

Trade/Device Name: Disposable Prophy Angle (3399-60, 3399-090, 3399-105)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: June 9, 2025
Received: June 18, 2025

Dear Jessica Mao:

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/pmnmn.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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251869

?

Please provide the device trade name(s).

?

Disposable Prophy Angle (3399-60, 3399-090, 3399-105)

Please provide your Indications for Use below.

?

Disposable Prophy Angle is intended to be attached to a low speed dental handpiece and used by professional dentists and dental hygienists for polishing and cleaning the surface of teeth. It is intended for single use, and should be discarded after each patient.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Premium Plus (Dongguan) Limited
Applicant Address	Flat 101, No.122, Tianqiao Road, Changping, Dongguan, Guangdong
Applicant Contact Telephone	86 769 83397277
Applicant Contact	Ms. Jessica Mao
Applicant Contact Email	jessicamao@premiumplushk.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Disposable Prophy Angle (3399-60, 3399-090, 3399-105)
Common Name	Dental handpiece and accessories
Classification Name	Handpiece, Contra- And Right-Angle Attachment, Dental
Regulation Number	872.4200
Product Code(s)	EGS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K100854	Premium Plus Disposable Prophy Angle	EGS

Device Description Summary

21 CFR 807.92(a)(4)

Disposable Prophy Angle is a dental rotational device that consists of a prophy cup, a plastic body, a gear and a shaft with gear, which connects to a low-speed dental handpiece. The gear has the prophy cup attached to the end which holds dental tooth polishing paste. Prophy Angle is held in a dental handpiece by a shaft, which rotates the device's gear at speed as the polishing/ cleaning paste is applied to the surface of the teeth.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Disposable Prophy Angle is intended to be attached to a low speed dental handpiece and used by professional dentists and dental hygienists for polishing and cleaning the surface of teeth. It is intended for single use, and should be discarded after each patient.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of Disposable Prophy Angle are the same as the predicate device, Premium Plus Disposable Prophy Angle (K100854).

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same indications for use, target uses, design, operation speed, operation principle and materials. They are single use and non-sterile device. Both are non- cytotoxic, non- sensitizing and non- irritating. The subject device and the predicate device are substantially equivalent with only minor differences. These minor differences do not constitute a new intended use or raise different issues of safety and effectiveness compared with the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing performed to establish substantial equivalence to the predicate device in accordance with ANSI/ADA specification No. 85, Part 1 Disposable Prophy Angle

Not Applicable

Based on the non-clinical tests, the proposed Disposable Prophy Angle is as safe, as effective, and performs as well as or better than the predicate device Premium Plus Disposable Prophy Angle(K100854).