November 7, 2022

AJK Engineering, Inc.
% Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K220346
Trade/Device Name: Lotus Prophy Angle
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: August 12, 2022
Received: August16, 2022

Dear Christine Scifert:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K220346

Device Name
Lotus Prophy Angle

Indications for Use *(Describe)*
The intended use of the Lotus Prophy Angle is for polishing and cleaning 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary
## Lotus Prophy Angle
## August 12, 2022

**Company:** AJK Engineering, Inc.
1605 Ashley Court
Sommerville, SC 29486
Phone: 888-962-1652

**Company Contact:** Ajay Kumar
ajay@lotus-dpa.com

**Official Correspondent:** Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

**Trade Name:** Lotus Prophy Angle

**Common Name:** Handpiece, Contra- And Right-Angle Attachment, Dental

**Classification:** Class I

**Regulation Number:** 21 CFR 872.4200

**Panel:** Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1)
Division of Dental and ENT Devices

**Product Code:** EGS

**Device Description:**
Lotus Prophy Angle is a device used for polishing and cleaning the surface of teeth. It consists of a pair of gears, a turning spindle and a drive spindle which can connect the low speed handpiece. The turning spindle has a prophylaxis cup on it for polishing or cleaning teeth.

Lotus Prophy Angle is intended for single use only and is provided aseptic in sealed packaging to be prevent contamination.

**Indications for Use**:
The intended use of the Lotus Prophy Angle is for polishing and cleaning teeth.

## Substantial Equivalence:

The subject device is substantially equivalent to the following predicate device:

Primary Predicate:

Pac-Dent International (Suzhou), Inc., ProAngle™ Disposable Prophy Angle, K030603

| Characteristic | Lotus Prophy Angle | Primary Predicate:<br>Pac-Dent International (Suzhou), Inc<br>ProAngle™ Disposable Prophy Angle |
|---|---|---|
| 510(k) Number | **SUBJECT** | **K030603** |
| Intended Use | Disposable Prophy Angle | Disposable Prophy Angle |
| Product Code | EGS | EGS |
| Indications for Use | The intended use of the Lotus Prophy Angle is for polishing and cleaning teeth. | The intended use of the ProAngle™ disposable prophy angle is for polishing and cleaning teeth. |
| Materials | Housing: Polycarbonate (PC)<br>Gears: Polyoxymethylene (POM)<br>Splatter guard: Silicone<br>Cups: Thermoplastic Elastomer (TPE)<br>Inserts: Polycarbonate (PC) | Housing: Polycarbonate (PC)<br>Gears: Polyoxymethylene (POM)<br>Splatter guard: Silicone<br>Cups: Thermoplastic Elastomer (TPE)<br>Inserts: Polycarbonate (PC) |
| Sterility | Non-Sterile | Non-Sterile |

The subject and predicate devices are identical in Intended Use, Technological Characteristics, Performance Specifications, and Material. Therefore, it can be concluded that the subject Lotus Prophy Angle does not raise new questions of safety and effectiveness when compared to the predicate devices.

## Performance Testing:

The subject Lotus Prophy Angle is identical in every way to the previously cleared ProAngle™ Disposable Prophy Angle (K030603). Therefore, all previous testing performed on the ProAngle™ Disposable Prophy Angle is applicable to the subject device. The following confirmatory testing was performed on the subject device in accordance with ANSI/ADA Specification No. 85-1 - *Disposable Prophy Angles*: Speed, Load, Temperature Rise, and Vibration Analysis.

## Conclusion:

Since the subject and predicate device are identical in every way, the subject device is determined to be substantially equivalent to the predicate device.