May 5, 2025

Asiga Pty Ltd
℅ Keely So
Senior Manager, Medical Devices / IVD (Consultant)
Pharmalex Pty Ltd
Level 10, 1 Chandos Street
St Leonards, NSW 2065
AUSTRALIA

Re: K243370
Trade/Device Name: DentaTOOTH
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: March 24, 2025
Received: March 24, 2025

Dear Keely So:

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
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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)*

K243370

Device Name

DentaTOOTH

Indications for Use *(Describe)*

Asiga DentaTOOTH is intended exclusively for professional dental work.
Asiga DentaTOOTH is a 3D print resin indicated for the manufacturing of 3D printed temporary crowns, bridges, inlays, onlays and veneers.

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) #: K243370

510(k) Summary

Prepared on: 2024-10-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Asiga Pty Ltd
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Correspondent Contact	Ms. Keely So
Correspondent Contact Email	keely.so@pharmalex.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DentaTOOTH
Common Name	Temporary crown and bridge resin
Classification Name	Crown And Bridge, Temporary, Resin
Regulation Number	872.3770
Product Code(s)	EBG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211101	E-Temp	EBG
K200039	P pro Crown & Bridge	EBG

Device Description Summary

21 CFR 807.92(a)(4)

DentaTOOTH is a resin material used by dental professionals for the manufacture of temporary dental restorations including temporary crowns, bridges, inlays, onlays and veneers. DentaTOOTH resin is available in six Vita shades A1, A2, A3, B1, B2, B3.

DentaTOOTH resins are used with digital light processing (DLP) based 3D printers to produce denture temporary dental restorations. DentaTOOTH resin has been validated for use with the Asiga Max Series and Pro Series printers for the manufacture of temporary dental restorations at 385nm wavelengths.

DentaTOOTH is a light-cure methacrylate-based resin with photoinitiator, UV absorber, dispersant and pigments. DentaTOOTH is a Type

2, Class 2 resin per ISO 10477:2020 and Type 1, Class 2, Group 2 resin per ISO 4049:2019.

DentaTOOTH has a shelf life of 36 months. The device may be stored in Asiga Max and Pro Series printers for up to 4 weeks with hood closed.

DentaTOOTH is compliant to ISO 10477:2020 and ISO 4049:2019 for polymer based crown and veneering materials, and polymer based restorative materials, respectively.

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

Asiga DentaTOOTH is intended exclusively for professional dental work.
Asiga DentaTOOTH is a 3D print resin indicated for the manufacturing of 3D printed temporary crowns, bridges, inlays, onlays and veneers.

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

The subject device and primary predicate are both indicated for the manufacturing of temporary dental restorations such as crowns and bridges. Crowns are dental restorations that fully encapsulate a tooth. Bridges are used to fill tooth gap(s) by mounting the restoration onto existing teeth. Compared to the predicate, the subject device has additional indications for inlays, onlays and veneers which are also temporary dental restorations. Inlays are those that fill an empty space between the cusps of a tooth while onlays are cover one or more cusps of a tooth. Onlays may also be referred to as partial crowns which is an indication of the predicate device. Veneers are shells that fit over the front surfaces of teeth.

Product code EBG under regulation 21 CFR 872.3770 is defined as:
'A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis such as a crown or bridge, for use until a permanent restoration is fabricated.'

The differences do not constitute a new intended use as inlays, onlays and veneers are still considered a type of temporary prosthesis used for temporary restorations.

As the primary predicate is indicated only for temporary crowns and bridges, a secondary predicate has been referenced to include indications for temporary inlays, onlays, and veneers. The secondary predicate device is P pro Crown & Bridge (K200039), which is a light curable resin indicated for the fabrication of veneers, inlays and onlays.

The subject device has been tested in accordance with ISO 10477:2020 Dentistry — Polymer-based crown and veneering materials and ISO 4049 Dentistry — Polymer-based restorative materials.

There are no differences between the subject and predicate devices with respect to classification, regulation number, product code, indications for use and prescription status.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices are resin materials intended for 3D printing of temporary device restorations. There are no differences between the subject and predicate devices with respect to classification, regulation number, product code, prescription status, resin type, product state, performance testing, and biocompatibility profile.

The subject and predicate devices differ in terms of material formulation. All devices rely on the same type of equipment comprising a scanner, design software, DLP-based 3D printer and post-curing unit as part of the temporary restoration manufacturing process, although the specific equipment itself differs. All resins have a different shelf life.

The subject device, DentaTOOTH, is substantially equivalent to the legally marketed primary predicate device, E-Temp (K211101) and secondary predicate device, P pro Crown & Bridge (K200039). The devices have similar indications for use and technological differences do not raise any new questions of safety or effectiveness. Therefore, DentaTOOTH is substantially equivalent to the predicates.

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

Nonclinical tests per performed in accordance with the below standards:
- ISO 10477:2020 Dentistry — Polymer-based crown and veneering materials (4-302)
- ISO 4049:2019 Dentistry — Polymer-based restorative materials (4-298)

Safety and performance of DentaTOOTH has been evaluated in accordance with ISO 10477:2020 Dentistry — Polymer-based crown and veneering materials:
• Depth of cure
• Surface finish
• Flexural strength
• Water sorption
• Solubility
• Shade consistency
• Color stability

Safety and performance of DentaTOOTH has also been evaluated in accordance with ISO 4049:2019 Dentistry — Polymer-based restorative materials
• Flexural strength
• Water sorption and solubility
• Shade of restorative materials
• Color stability after irradiation and water sorption
• Shade of restorative materials

All tests conducted demonstrated compliance with the above referenced standards.DentaTOOTH was subjected to validation of packaging (according to ASTM D4169-22 / 14-576), shelf life, and biocompatibility according to ISO 10993-1:2018 / 2-258 and its relevant parts).

Not Applicable.

All tests demonstrated acceptable results and did not raise any new questions of safety or efficacy for DentaTOOTH. Therefore performance characteristics are considered equivalent to the primary predicate device, E-Temp (K211101) and secondary predicate device, P pro Crown & Bridge (K200039).