April 11, 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: K243356
Trade/Device Name: Asiga DentaBASE
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: March 7, 2025
Received: March 7, 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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OHT1: Office of Ophthalmic, Anesthesia,
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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)*

K243356

Device Name

Asiga DentaBASE

Indications for Use *(Describe)*

Asiga DentaBASE is intended exclusively for professional dental work.
Asiga DentaBASE is a 3D print resin intended for the manufacturing of 3D printed denture bases.
The denture bases produced are suitable for dental indications including removable dentures.

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) #: K243356

510(k) Summary

Prepared on: 2025-04-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Asiga Pty Ltd
Applicant Address	Unit 2, 19-21 Bourke Road Alexandria NSW 2015 Australia
Applicant Contact Telephone	02 9690 2737
Applicant Contact	Mr. Justin Elsey
Applicant Contact Email	justin@asiga.com
Correspondent Name	Pharmalex Pty Ltd
Correspondent Address	Level 10, 1 Chandos Street St Leonards NSW 2065 Australia
Correspondent Contact Telephone	+61 2 9906 2984
Correspondent Contact	Ms. Keely So
Correspondent Contact Email	keely.so@pharmalex.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Asiga DentaBASE
Common Name	Denture relining, repairing, or rebasing resin
Classification Name	Resin, Denture, Relining, Repairing, Rebasing
Regulation Number	872.3760
Product Code(s)	EBI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K191497	NextDent Denture 3D+	EBI

Device Description Summary

21 CFR 807.92(a)(4)

Asiga DentaBASE resins are used with digital light processing (DLP) based 3D printers to produce denture bases. DentaBASE resin has been validated for use with the Asiga Max Series and Pro Series printers.

Asiga DentaBASE is a Type 4 light-cure methacrylate-based resin with photoinitiator, UV absorber, dispersant and pigments.

Asiga DentaBASE resin material is used in a DLP 3D printer, which prints the denture base from CAD data. The denture base is built by solidifying successive layers of photopolymer against each other. Each layer is light cured before adding the next layer, with post-curing in a light chamber unit. The 3D printer and light-curing unit are not included with the device.

The device is supplied as a pre-mixed resin in one color, natural pink. The device is supplied non-sterile, and it not intended to be sterilized.

Asiga DentaBASE has a shelf life of 36 months.

AsigaDentaBASE is compliant to ISO 20795-1 for Type 4 materials.

AsigaDentaBASE is a surface device with mucosal membrane contact for >30 days and is compliant to ISO 10993-1 and ISO 7405.

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

Asiga DentaBASE is intended exclusively for professional dental work.
Asiga DentaBASE is a 3D print resin intended for the manufacturing of 3D printed denture bases.
The denture bases produced are suitable for dental indications including removable dentures.

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

The subject and predicate devices have the same indications for use. Both devices are 3D print resin materials intended for the manufacturing of 3D printed denture bases.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices are both 3D print resin materials used specifically for the manufacture of denture bases. There are no differences between the subject and predicate devices with respect to classification, regulation number, product code, prescription status, indications for use, resin type, product state, performance testing, biocompatibility profile, and sterility status.

The subject and predicate devices differ in terms of material formulation. Both 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 denture base manufacturing process, although the specific equipment itself differs. Both resins utilise different bonding agents for teeth assembly and have a different shelf life.

The subject device, DentaBASE resin is substantially equivalent to the legally marketed predicate device, NextDent Denture 3D+ (K191497). Substantial equivalence to performance specifications outlined in FDA Guidance: Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway (April 13, 2022) has also been considered. Both subject and predicate devices have similar indications for use and technological differences do not raise any new questions of safety or effectiveness. Therefore, DentaBASE is substantially equivalent to the predicate.

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

DentaBASE was tested in accordance with requirements per FDA guidance "Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway" and ISO 20795-1:2013 (4-232). DentaBASE 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. Testing conducted did not raise any new questions of safety or efficacy. All ISO 20795-1 performance criteria as referenced in FDA guidance 'Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway (April 13, 2022) were considered. The following bench tests were conducted on DentaBASE resin: ultimate flexural strength, flexural modulus, water sorption, water solubility, residual monomer, and biocompatibility. Therefore, performance characteristics are considered equivalent to the predicate device NextDent Denture 3D+ (K191497).