May 12, 2026

Promimic AB
Oscar Davidsson
Head of Quality Assurance/Regulatory Affairs Officer
Entreprenörsstråket 10
Mölndal, Västergötland 43153
SWEDEN

Re: K252731
Trade/Device Name: Promimic ZrP Surface Dental Implant; Promimic ZrP + HAnano Surface Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 21, 2026
Received: April 21, 2026

Dear Oscar Davidsson:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANDREW I. STEEN -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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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)*

K252731

Device Name

Promimic ZrP Surface Dental Implant;
Promimic ZrP + HAnano Surface Dental Implant

Indications for Use *(Describe)*

The Promimic ZrP Surface Dental Implant and Promimic ZrP + HAnano Surface Dental Implant are intended for surgical placement into the bone of upper/lower jaw arches as permanent anchorages for prosthetic devices and to restore chewing function. The Promimic ZrP Surface Dental Implant and Promimic ZrP + HAnano Surface Dental Implant can be immediately loaded only with good primary stability and appropriate occlusal loading. The Promimic ZrP Surface Dental Implants and Promimic ZrP + HAnano Surface Dental Implants are only to be used with straight abutments, namely the following components from the Ospol Dental Implant System (K070184):
Abutment System Name: Ospol Dental Implant System (K070184) - Straight abutments (regular platform). Platform Diameter: Ø4.0 mm (regular platform).
Compatible Ospol Components (regular platform only):
- Cover Screw (#1014)
- Abutment screw (#3000)
- Standard abutment, low (#3001)
- Standard abutment, high (#3008)
- Anatomic abutment, high (#3004)
- Anatomic abutment, low (#3005)
- Healing abutment, high (#3006)
- Healing abutment, low (#3007)

Platform Diameter: Ø4.0 mm (regular platform).

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.

510(k) Summary
Promimic AB
Promimic ZrP Surface Dental Implant & Promimic ZrP + HA^{nano} Surface Dental Implant

ADMINISTRATIVE INFORMATION

Submitter:	Promimic AB Entreprenörsstråket 10 431 53 Mölndal Sweden Phone: +46 73 370 98 28 Email: oscar.davidsson@promimic.com
Contact Person:	Oscar Davidsson Regulatory Affairs Officer
Date Summary Prepared:	May 11, 2026

DEVICE NAME AND CLASSIFICATION

Trade or Proprietary Name:	Promimic ZrP Surface Dental Implant Promimic ZrP + HA^{nano} Surface Dental Implant
Common Name:	Promimic ZrP Surface Dental Implant Promimic ZrP + HA^{nano} Surface Dental Implant
Regulation Number:	21 CFR 872.3640
Regulation Name:	Endosseous dental implant
Regulatory Class:	Class II
Product Code:	DZE

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K101225, Promimic Dental Implant

Reference Devices
K142260, Nobel Biocare – NobelActive TiUnite
K070184, Ospol Dental Implant System

DEVICE DESCRIPTION

Promimic ZrP Surface Dental Implant

The Promimic ZrP Surface Dental Implant is a titanium dental screw designed for surgical placement into the bone of upper and lower jaw arches. It serves as a permanent anchorage for prosthetic devices to restore chewing function. The device is immediately loadable with good primary stability and appropriate occlusal loading.

The Promimic ZrP Surface Dental Implant integrates with bone through osseointegration, a biological process where the titanium implant surface interacts with bone tissue. The implant is surface treated using Promimic's ZrP Surface Coating Liquid, a zirconium phosphate (ZrP)-based nanoscale surface treatment.

Material Composition: Titanium (conforming to ASTM F67 (Grade IV) and/or ISO 5832-2) screw with a ZrP nanocoating.

Physical Properties: Available in Ø4.0 mm, lengths 8.0, 10.0, 12.0, and 15.0 mm.

Surface Characteristics: Nano-sized ZrP coating.

Promimic ZrP + HA^{nano} Surface Dental Implant

The Promimic ZrP + HA^{nano} Surface Dental Implant is a titanium dental screw designed for surgical placement into the bone of upper and lower jaw arches. It serves as a permanent anchorage for prosthetic devices to restore chewing function. The device is immediately loadable with good primary stability and appropriate occlusal loading.

The Promimic ZrP + HA^{nano} Surface Dental Implant integrates with bone through osseointegration, a biological process where the titanium implant surface interacts with bone tissue. The implant is surface treated using Promimic's ZrP Surface Coating Liquid, a zirconium phosphate (ZrP)-based nanoscale surface treatment as well as using Promimic's LT-HA Surface Coating Liquid.

Material Composition: Titanium (conforming to ASTM F67 (Grade IV) and/or ISO 5832-2) screw with a ZrP and HA nanocoating.

Physical Properties: Available in Ø4.0 mm, lengths 8.0, 10.0, 12.0, and 15.0 mm.

Surface Characteristics: Nano-sized ZrP and HA coating.

INDICATIONS FOR USE

The Promimic ZrP Surface Dental Implant and Promimic ZrP + HA^{nano} Surface Dental Implant are intended for surgical placement into the bone of upper/lower jaw arches as permanent anchorages for prosthetic devices and to restore chewing function. The Promimic ZrP Surface Dental Implant and Promimic ZrP + HA^{nano} Surface Dental Implant can be immediately loaded only with good primary stability and appropriate occlusal loading. The Promimic ZrP Surface Dental Implants and Promimic ZrP + HA^{nano} Surface Dental Implants are only to be used with straight abutments, namely the following components from the Ospol Dental Implant System (K070184):

Abutment System Name	Platform Diameter
Ospol Dental Implant System (K070184) – straight abutments (regular platform)	⌀ 4.0 mm (regular platform)

Compatible Ospol Components (regular platform only)	Platform diameter
Cover screw (#1014); Abutment screw (#3000); Standard abutment, low (#3001); Standard abutment, high (#3008); Anatomic abutment, high (#3004); Anatomic abutment, low (#3005); Healing abutment, high (#3006); Healing abutment, low (#3007)	⌀ 4.0 mm (regular platform)

SUBSTANTIAL EQUIVALENCE DISCUSSION

The Promimic ZrP Surface Dental Implant and Promimic ZrP + HA^{nano} Surface Dental Implant are substantially equivalent to the legally marketed predicate/reference devices K101225 (Promimic Dental Implant), K142260 (Nobel Biocare NobelActive TiUnite), and K070184 (Ospol Dental Implant System). The subject devices share the same intended use as endosseous dental implants for surgical placement in the upper or lower jaw to provide permanent anchorage for prosthetic restorations and restore chewing function. Immediate loading is indicated only when good primary stability and appropriate occlusal loading are present.

A side-by-side comparison of key non-proprietary technological characteristics is provided below.

Feature	Subject Devices	Predicate/Reference Devices	Comparison
Intended use / loading protocol	Endosseous dental implants intended for surgical placement into the upper/lower jaw arches as permanent anchorages for prosthetic devices and to restore chewing function. Immediate loading only with good primary stability and appropriate occlusal loading.	Root-form/endosseous dental implants intended for surgical placement in the jaw to support prosthetic devices and restore chewing function. Predicate devices also include immediate loading indications where appropriate.	No difference in intended use.
Compatible abutment system	Use limited to straight abutments and specified regular-platform components from the Ospol Dental Implant System (K070184), Ø 4.0 mm regular platform.	Ospol Dental Implant System (K070184) is a legally marketed implant system with compatible connection components.	Narrowed public compatibility claim to specified Ospol straight-abutment components only.
Material	Commercially pure titanium (Grade IV).	Commercially pure titanium (Grade IV).	Identical base material.
Surface treatment	ZrP Surface device: zirconium phosphate nanocoating. ZrP + HA^{nano} Surface device: zirconium phosphate and hydroxyapatite nanocoating.	Promimic Dental Implant (K101225): HA^{nano} surface; NobelActive TiUnite (K142260): anodized/phosphorylated titanium surface; Ospol (K070184): calcium-deposited oxidized surface.	Different surface treatments, but same intended use and no new questions of safety or effectiveness.
Sterility / delivery	Provided sterile and packaged in sterile packaging.	Provided sterile and packaged in sterile packaging.	No difference.

Feature	Subject Devices	Predicate/Reference Devices	Comparison
Design / connection	Screw-type root-form endosseous implants with internal conical connection.	Promimic Dental Implant (K101225): screw-type root-form implant with external hex connection. NobelActive and Ospol: screw-type root-form implants with internal conical connection.	No difference in overall implant archetype; connection type matches NobelActive and Ospol.
Size options	Diameter: 4.0 mm. Lengths: 8.0, 10.0, 12.0, and 15.0 mm.	K101225: 3.75 mm diameter, 8.5–15.0 mm lengths. K142260: 3.0–5.5 mm diameters, 7.0–18.0 mm lengths. K070184: 4.0 mm diameter, 8–15 mm lengths.	Within clinically accepted ranges of legally marketed devices.

PERFORMANCE DATA

Non-clinical performance information submitted, referenced, or relied upon to support substantial equivalence included the following:

- **Biocompatibility:** Biological evaluation according to ISO 10993-1 (including ISO 10993-5, -10, and -23) demonstrated acceptable biocompatibility.
- **Sterilization / sterility support:** Devices are supplied sterile via gamma radiation. Sterilization validation was performed in accordance with EN ISO 11137-2 and EN ISO 17025. The sterilization cycle achieved a Sterility Assurance Level (SAL) of 10^{-6}. Finished sterile devices were also evaluated for bacterial endotoxins by BET/LAL in accordance with USP <85>, using the gel-clot method (equivalent to Ph. Eur. 2.6.14 Method A), with an acceptance criterion of ≤ 20 EU/device. Tested finished-device configurations met the selected endotoxin limit.
- **Shelf life / package validation:** Accelerated aging to support a claimed 5-year shelf life was performed in accordance with ASTM F1980, with package integrity evaluations including tensile strength and dye penetration.
- **MRI safety information:** Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. “Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices.” Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The rationale addressed parameters per the FDA Guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”, including magnetically induced displacement force and torque.
- **Implant-abutment compatibility:** Compatibility of the proposed implant body devices with the specified straight abutment components from the Ospol Dental Implant System (K070184) was supported through evaluation of OEM engineering drawings, dimensional tolerances, and comparison of critical implant-abutment and abutment screw interface features. This information supported compatibility of the subject

devices with the specified regular-platform Ospol straight-abutment components described in the submission.

- **Bench and materials characterization:** Additional non-clinical testing included coating adhesion and mechanical stability following insertion/removal in simulated bone, X-ray diffraction phase characterization of the ZrP- and HA-derived coating materials, cross-sectional coating structure/thickness characterization, and interferometry surface roughness characterization. These data supported coating integrity and characterization of the final surface technologies.

An assessment of clinical performance data was not necessary to support the determination of substantial equivalence.

CONCLUSION

Based on the information provided in the 510(k) submission, the Promimic ZrP Surface Dental Implant and Promimic ZrP + HA^{nano} Surface Dental Implant are substantially equivalent to the identified legally marketed predicate/reference devices. Differences in technological characteristics do not raise new questions of safety or effectiveness.