December 1, 2020

Z-Systems AG
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K201712
Trade/Device Name: Z5-TL
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 3, 2020
Received: November 4, 2020

Dear Kevin Thomas:

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,

Andrew Steen
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201712

Device Name

Z5-TL

Indications for Use *(Describe)*

Z5-TL implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5-TL implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-TL implants are intended for delayed loading.

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.

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510(k) Summary

Z5-TL

Z-Systems AG

November 20, 2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	Z-Systems AG Werkhofstrasse 5 CH-4702 Oensingen Switzerland Telephone +41 62 388 69 69
Official Contact	Rubino DiGirolamo, CEO
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Z5-TL
Common Name	Dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device: K190243, Z5-BL, Z-Systems AG
Reference Devices:
K132881, Z5c, Z-Systems AG
K063286, OSSEOTITE® Dental Implants, Implant Innovations, Incorporated
K072642, BIOMET 3i Dental Abutments and Restorative Components, BIOMET 3i, Incorporated

INDICATIONS FOR USE STATEMENT

Z5-TL implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5-TL implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-TL implants are intended for delayed loading.

SUBJECT DEVICE DESCRIPTION

Z5-TL is a dental implant system that includes root-form, endosseous threaded dental implants indicated for tissue level placement. The dental implants are provided in two endosseous body diameters (4 mm and 5 mm) and each diameter is provided in three endosseous lengths (8 mm, 10 mm, and 12 mm). The corresponding platform diameters are: 4.8 mm platform diameter for 4 mm body diameter, and 6 mm platform diameter for 5 mm body diameter. The dental implants are manufactured from Y-TZP zirconia conforming to ISO 13356. The system also includes gingiva formers and a temporary abutment manufactured from polyetheretherketone (PEEK). Zirconia abutments for single-unit and multi-unit cemented restorations are provided in straight and 15° angled designs. For retention of overdentures, zirconia Locator-type abutments are provided in straight and 15° angled designs.

The subject device is compatible with the following components cleared in K190243: a healing cap manufactured from PEEK; Locator-type abutments manufactured from zirconia; and occlusal (abutment) screws manufactured from zirconia and from Ti-6Al-4V alloy conforming to ASTM F136.

The subject device implants are provided sterilized by plasma gas. All other subject device components are to be sterilized by the end user by moist heat (steam).

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 14937 and ISO 17665-1 (referenced from K132881); sterile product shelf life testing according to ISO 11607-1, ISO 11607-2, ASTM F1886/F1886M, and ASTM D3078 (referenced from K132881); biocompatibility of the PEEK material according to ISO 10993-3, ISO 10993-5, ISO 10993-12, ISO 10993-10, ISO 19003-11, ISO 10993-18, and USP Class VI testing according to USP 37-NF32 <88> (referenced from K190243); static compression and compression fatigue testing of the subject device zirconia implants and zirconia abutments according to ISO 14801; assessment of abutment screw loosening and abutment screw removal torque testing (according to ISO 18130) after insertion to the torque recommended in the subject device labeling, and after dynamic testing according to ISO 14801, including microscopic examination of the abutment screws and internal threads of the implant bodies, and comparison to the reference devices K063286 and K072642; and data leveraged from K190243 that included an assessment of wear particles associated with the subject device Ti-6Al-4V alloy abutment screw used with the subject device zirconia implant bodies and zirconia abutments after dynamic testing according to ISO 14801, including examination by light microscopy and scanning electron microscopy with energy dispersive X-ray analysis (SEM / EDX), and comparison to all-titanium constructs of the reference devices K063286 and K072642.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the additional predicate device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the additional predicate device.

The subject device is substantially equivalent in intended use to the primary predicate K190243, and to the reference device K132881. All are intended for use in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. In addition, all are intended for a delayed loading treatment protocol.

Except for the names of the devices, the Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate device K190243 and to the additional predicate device K132881. Minor differences in the exact wording of the IFUS do not impact substantial equivalence.

The primary predicate device K190243 is for support of substantial equivalence of the subject device dental implant design. The subject device dental implants and the primary predicate device K190243 implants have an identical internal abutment interface design, including the same hexagonal indexing and threaded connection. The primary predicate device K190243 also is for support of substantial equivalence in terms of similar designs and identical material for the subject device temporary abutment and gingiva formers components manufactured from polyetheretherketone (PEEK), and the subject device Locator-type abutments manufactured from zirconia. The primary predicate device K190243 also is for support of substantial equivalence in terms of previously-cleared components that are compatible with the subject device, including the healing cap, the Locator-type abutments, and the abutment screws.

The additional predicate device K132881 is for support of substantial equivalence of the subject device tissue level implant design. The subject device dental implants and the implants cleared in the additional predicate device K132881 have the same implant body diameters, the same implant platform diameters, the same thread design, and the same endosseous threaded lengths.

The subject device implants and abutments are manufactured from yttria-stabilized zirconia (Y-TZP) conforming to ISO 13356, *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*, using the identical material and processing used for zirconia components cleared in the predicate devices K190243 and K132881. The subject device dental implants also have an identical endosseous threaded surface (grit-blasted and laser modified) as the implants cleared in the predicate devices K190243 and K132881. The subject device PEEK temporary abutment and PEEK gingiva formers are manufactured using the identical material and processes as PEEK components cleared in the primary predicate K190243.

The additional predicate device K132881 also is for support of substantial equivalence of the subject device in terms of sterilization and shelf life (and referenced in K190243). The subject device dental implants are provided to the end user sterilized by plasma gas. The subject device implants use the same packaging and have the same sterile barrier shelf life as the sterile components cleared in K132881 (and referenced in K190243). The processes to monitor, control, and test for bacterial endotoxins for the subject device are the same as K190243.

All other subject device components (zirconia abutments, PEEK gingiva former, and PEEK temporary abutment) are to be sterilized by the end-user. The moist heat sterilization cycles recommended in the labeling have been validated in a prior Z-Systems AG submission (K120793), and the subject device components do not represent a new worst-case for sterilization. Dimensional analysis was conducted for

both methods of sterilization to verify that the subject device does not introduce a new worst case. The sterilization process is the same used for the primary predicate K190243.

Mechanical performance testing of the subject device dental implants and abutments was performed according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* The fatigue limit data demonstrated that the subject device constructs have sufficient strength for their intended use.

Minor differences in the designs, dimensions, or sizes among the subject device, the primary predicate device, and the additional predicate device do not affect substantial equivalence. These minor differences do not impact safety or effectiveness because these differences are related to the specific designs features and system components and these differences are mitigated by the mechanical performance testing.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate device have the same intended use, have similar technological characteristics, and are made of identical materials. The subject device, the primary predicate, and additional predicate device encompass the same range of physical dimensions, are packaged in the same materials, and are sterilized using the same methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence

	Subject Device	**Primary Predicate**	**Additional Predicate Device**
	Z5-TL Z-Systems AG	K190243 Z5-BL Z-Systems AG	K132881 Z5c Z-Systems AG
Indications for Use Statement	Z5-TL implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5-TL implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-TL implants are intended for delayed loading.	Z5-BL implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5-BL implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-BL implants are intended for delayed loading.	Z5c implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5c implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them. Z5c implants are intended for delayed loading.
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate Device	**Not applicable**	**IFU Statement; implant design, material, surface; abutment design, materials, sterilization**	**Implant design; sterilization and shelf life**
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA
Components	Implants, abutments	Implants, abutments, abutment screws	Implants, abutments (the abutment is cemented to the implant)
Implant Designs			
Implant Diameter, mm	4.0, 5.0	4.0, 5.0	4.0, 5.0
Implant Platform diameter, mm	4.8, 6.0	4.0, 5.0	4.8, 6.0
Implant Endosseous Length, mm	8, 10, 12	8, 10, 12	8, 10, 12
Implant Material	Y-TZP, ISO 13356	Y-TZP, ISO 13356	Y-TZP, ISO 13356
Implant Surface	Grit-blasted and laser modified	Grit-blasted and laser modified	Grit-blasted and laser modified
Abutment / Prosthetic Component Designs			
Features	*Subject device* Indexed, straight and angled (15°) Indexed Locator-type, angled (15°) Non-indexed Locator-type, straight *Previously cleared compatible* Indexed Locator-type, angled (15°) Non-indexed Locator-type, straight	Indexed, straight and angled (15°) Non-indexed straight Indexed Locator-type, angled (15°) Non-indexed Locator-type, straight	Non-indexed straight Non-indexed angled (15°)
Prosthesis Attachment	*Subject device* Cement-retained Locator-type attachment *Previously cleared compatible* Cement-retained Locator-type attachment	Cement-retained Locator-type attachment	Cement-retained
Restoration	Single-unit; Multi-unit	Single-unit; Multi-unit	Single-unit; Multi-unit
Prosthetic platform diameter, or Coronal diameter	*Subject device* 3.6 – 6.6 mm *Previously cleared compatible* 4.4 mm	4.5 – 6.5 mm	3.6 mm

	Subject Device	**Primary Predicate**	**Additional Predicate Device**
	Z5-TL Z-Systems AG	K190243 Z5-BL Z-Systems AG	K132881 Z5c Z-Systems AG
Abutment angle	Straight (0°), 15°	Straight (0°), 15°	Straight (0°), 15°
Abutment material	Y-TZP, ISO 13356	Y-TZP, ISO 13356	Y-TZP, ISO 13356
Abutment screw material	*Previously cleared compatible screws* Y-TZP, ISO 13356 Ti-6Al-4V alloy, ASTM F136	Y-TZP, ISO 13356 Ti-6Al-4V alloy, ASTM F136	Not applicable (the abutment is cemented to the implant)
Sterilization Status/Method			
Implants	Provided sterile to end user / plasma gas sterilized	Provided sterile to end user / plasma gas sterilized	Provided sterile to end user / plasma gas sterilized
Abutments and Prosthetic Components	*Previously cleared compatible* Healing Cap: Provided sterile to end user / plasma gas sterilized Abutment screws: Provided non-sterile to end user / moist heat (steam) sterilization required *All other subject device abutments and prosthetic components:* Provided non-sterile to end user / moist heat (steam) sterilization required	Healing Cap: Provided sterile to end user / plasma gas sterilized All other: Provided non-sterile to end user / moist heat (steam) sterilization required	Provided non-sterile to end user / dry heat sterilization required