October 14, 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: K200386
Trade/Device Name: Z5-BL
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 11, 2020
Received: September 14, 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,

for Srinivas Nandkumar, Ph.D.
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)*

K200386

Device Name

Z5-BL

Indications for Use *(Describe)*

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.

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

K200386

Z5-BL

Z-Systems AG

September 11, 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-BL
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
K131701, Z5mlb and Z5mlc, Z-Systems AG
K120793, Z-Look3 Evo SLM, Z-Systems AG

INDICATIONS FOR USE STATEMENT

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.

SUBJECT DEVICE DESCRIPTION

Z5-BL is a dental implant system that includes root-form, endosseous threaded dental implants indicated for bone level placement. The subject device includes dental implants provided in one body diameter of 3.6 mm in lengths of 8 mm, 10 mm, and 12 mm. The subject device also includes a gingiva former, straight abutments for single-unit cemented restorations, and a 15° angled abutment also for single-unit cemented restorations.

The subject device is compatible with components cleared previously in K190243, including a healing cap, straight abutments for multi-unit cemented restorations, Locator-type abutments for retention of overdentures, and occlusal (abutment) screws.

The subject device dental implants are manufactured from Y-TZP zirconia conforming to ISO 13356. The subject device abutments are manufactured from Y-TZP zirconia conforming to ISO 13356, or from polyetheretherketone (PEEK).

The subject device implants are provided sterilized by plasma gas. All other 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 (referenced from K132881) and ISO 17665-1 (referenced from K120793);

sterile product shelf life testing according to ISO 11607-1, ISO 11607-2, ASTM F1886/F1886M, and ASTM D3078 (referenced from K132881);

bacterial endotoxin testing for subject devices provided sterile (*Limulus* Amebocyte Lysate (LAL) test according to USP 40-NF 35 <85>, referenced from K190243);

biocompatibility of the yttria-stabilized zirconia (Y-TZP) conforming to ISO 13356 used to manufacture the subject device dental implants and abutments (referenced from identical material used for dental implants and abutments cleared in K190243);

biocompatibility endosseous threaded surface of the subject device implants (referenced from identical Al_2O_3 grit blasted and laser modified surface applied to the dental implants cleared in K190243);

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 according to ISO 14801 of the subject device zirconia implants and zirconia abutments, with both zirconia and titanium alloy abutment screws;

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 (referenced from K190243);

assessment of wear particles associated with the Ti-6Al-4V alloy abutment screw used with 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) (referenced from K190243).

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 reference devices 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 reference devices.

The subject device is substantially equivalent in intended use to the primary predicate K190243, and to the reference devices K132881 and K131701. All are intended for use in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The subject device and the primary predicate device K190243 are made of identical materials (implants and abutments). The subject device dental implants and the primary predicate device K190243 dental implants have an identical endosseous threaded surface (grit-blasted and laser modified), have the same internal implant connection features, and the same implant lengths. The subject device and the primary predicate device K190243 also include straight and angled abutments for cement-retained, single-unit restorations. Differences between subject device and the primary predicate device K190243 include the implant diameter (subject device 3.6 mm) and implant platform diameter (subject device also 3.6 mm). None of these minor design differences impact safety or effectiveness or change the intended use of the device.

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

The reference device K131701 is for support of substantial equivalence of the subject device in terms of the smaller dental implant body diameter and corresponding implant platform diameter (both 3.6 mm). The subject device dental implants and the reference device K131701 dental implants also are made of identical materials, and have the identical endosseous threaded surface (grit-blaster and laser modified).

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

Minor differences in the designs, dimensions, sizes, or materials among the subject device, the primary predicate device, and the reference devices 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 are mitigated by the mechanical performance testing.

CONCLUSION

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

Table of Substantial Equivalence

Comparison	**Subject Device**	**Primary Predicate**	**Reference Device**	**Reference Device**
	K200386 Z5-BL Z-Systems AG	K190243 Z5-BL Z-Systems AG	K132881 Z5c Z-Systems AG	K131701 Z5mlb and Z5mlc Z-Systems AG
Indications for Use Statement	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.	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.	Z5mlb: Z5mlb implants arc designed for surgical implantation into the edentulous upper and lower jaw for the attachment of dentures to replace missing teeth. Z5mlb implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them. Z5mlc: Z5mlc implants are designed for surgical implantation into the edentulous upper and lower jaw for the attachment of dentures to replace missing teeth. Z5mlc implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.
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	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/ Reference Device	Not applicable	IFU Statement; implant design, material, surface; abutment design	Reference for sterilization and shelf life	Reference for implant diameter (3.6 mm)
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE
Components	Implants, abutments	Implants, abutments, abutment screws	Implants, abutments (abutment cemented to implant)	One-piece implants
Implant Designs				
Implant Diameter, mm	3.6	4.0, 5.0	4.0, 5.0	3.6, 4.0
Implant Endosseous Length, mm	8, 10, 12	8, 10, 12	8, 10, 12	8, 10
Platform diameter, mm	3.6	4.0, 5.0	4.0, 5.0	Not applicable
Implant Material	Y-TZP	Y-TZP	Y-TZP	Y-TZP
Implant Surface	Grit-blasted and laser modified	Grit-blasted and laser modified	Grit-blasted and laser modified	Grit-blasted and laser modified
Abutment Designs				
Features	*Subject device* Indexed, straight and angled *Previously cleared compatible* Non-indexed straight; Indexed and Non-indexed Locator-type	Indexed, straight and angled; Non-indexed straight; Indexed and Non-indexed Locator-type	Non-indexed straight Non-indexed angled 15°	Ball-type attachment; Locator-type attachment
Prosthesis Attachment	*Subject device* Cement-retained *Previously cleared compatible* Cement-retained; Locator-type attachment	Cement-retained; Locator-type attachment	Cement-retained	Ball-type attachment; Locator-type attachment
Restoration	Single-unit; Multi-unit	Single-unit; Multi-unit	Single-unit; Multi-unit	Multi-unit

Comparison	**Subject Device**	**Primary Predicate**	**Reference Device**	**Reference Device**
	K200386 Z5-BL Z-Systems AG	K190243 Z5-BL Z-Systems AG	K132881 Z5c Z-Systems AG	K131701 Z5mlb and Z5mlc Z-Systems AG
Prosthetic platform diameter, mm	*Subject device* 3.8 mm – 4.3 mm *Previously cleared compatible* 4.5 mm	4.5 mm – 6.5 mm	3.6 mm	Not applicable
Abutment angle	Straight (0°), 15°	Straight (0°), 15°	Straight (0°), 15°	Straight (0°)
Abutment material	Y-TZP	Y-TZP	Y-TZP	Y-TZP
Abutment Screw Material	*Previously cleared compatible* Y-TZP Ti-6Al-4V alloy	Y-TZP Ti-6Al-4V alloy	Not applicable	Not applicable
Sterilization Status/Method				
Implants	Sterile / plasma gas	Sterile / plasma gas	Sterile / plasma gas	Sterile / plasma gas
Abutments	Non-sterile / moist heat (steam)	Healing Cap: Sterile / plasma gas All other: Non-sterile / moist heat (steam)	Non-sterile / Dry heat	Not applicable
Other Components	Not applicable	Non-sterile / moist heat (steam)	Non-sterile / moist heat (steam)	Not applicable