January 3, 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: K190243
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: December 3, 2019
Received: December 4, 2019

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190243

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

K190243

Z5-BL

Z-Systems AG

January 2, 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
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device:
K132881, Z5c, Z-Systems AG

Reference Devices:
K131701, Z_5mlb and Z_5mlc, Z-Systems AG
K153509, GPS® Angled Abutment, Implant Direct Sybron Manufacturing, LLC
K121131, Straumann Bone Level Ø4.1 mm and Ø4.8 mm Regular Connection (RC) Roxolid Dental Implants, Straumann USA
K172668, W Zirconia Implants, TAV Medical Ltd.
K063286, OSSEOTITE® Dental Implants, Implant Innovations, Incorporated
K072642, BIOMET 3i Dental Abutments and Restorative Components, BIOMET 3i, Incorporated

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 dental implants are provided in body diameters of 4 mm and 5 mm, and each diameter is provided in 8, 10, and 12 mm lengths. The dental implants are manufactured from Y-TZP zirconia conforming to ISO 13356. The system also includes a healing cap, 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. Occlusal (abutment) screws are provided in Ti-6Al-4V alloy conforming to ASTM F136 and in zirconia.

The subject device implants and Healing Cap 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 and ISO 17665-1 (referenced from K132881); sterile product shelf life testing according to ISO 11607-1, ISO 11607-2, ASTM F1886/F1886M-16, and ASTM D3078-02 (referenced from K132881); bacterial endotoxin testing according to USP 40-NF 35 <85>; biocompatibility testing of the PEEK material according to ISO 10993-3 (genotoxicity), ISO 10993-5 (cytotoxicity), ISO 10993-10 (irritation and sensitization), ISO 19003-11 (acute systemic toxicity and subacute/subchronic systemic toxicity), ISO 10993-18 (extraction of organic substances), and USP Class VI testing according to USP 37-NF32 <88>; confirmatory biocompatibility testing of the final finished PEEK and Ti-6Al-4V alloy devices according to ISO 10993-5 and ISO 10993-12; static compression and compression fatigue testing of the subject device zirconia implants, zirconia abutments, zirconia abutment screws, and Ti-6Al-4V alloy abutment screws 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 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-4titanium 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 reference devices listed above. Provided at the end of this summary are tables 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 K132881, and to the reference devices K131701, K153509, K121131, and K172668. 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 predicate device K132881 are made of identical materials, have the identical endosseous threaded surface (grit-blasted and laser modified), and have the same implant body diameters, implant platform diameters, and implant lengths. The subject device and the predicate device K132881 also include straight and angled abutments for cement-retained, single-unit and multi-unit restorations. Differences between subject device and the predicate device K132881 include: the fixation of the abutments to the implant (screws for subject device, cement for K132881); the subject device includes indexed abutments (K132881 includes only non-indexed abutments); and the subject device includes Locator-type abutments for attachment of overdentures. None of these minor design differences impact safety or effectiveness or change the intended use of the device.

The reference device K131701 is for support of substantial equivalence of the subject device straight (0°) Locator-type abutment design. The subject device and the reference device K131701 also are made of identical materials (implants and abutments), and have the identical endosseous threaded surface (grit-blaster and laser modified). Similarly, the reference device K153509 is for support of substantial equivalence of the subject device 15° angled Locator-type abutment design.

The reference device K121131 is for support of substantial equivalence of the subject device implants indicated for bone level placement. The previously cleared Z-Systems AG dental implants (K132281 and K131701) are indicated for tissue level placement.

The reference device K172668 is for support of substantial equivalence of the subject device use of a titanium alloy abutment screw with a zirconia dental implant fixture.

The reference devices K063286 and K072641 are for support of substantial equivalence of screw removal torque and wear particle analysis following dynamic mechanical testing.

The subject device dental implants and Healing Cap are provided sterilized by plasma gas, identical to the sterilization process for K132881 and K131701. 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.

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 or similar 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.

Substantial Equivalence – Indications for Use Statement

Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device
Z5-BL Z-Systems AG	K132881 Z5c Z-Systems AG	K131701 Z5mlb and Z5mlc Z-Systems AG	K153509 GPS® Angled Abutment Implant Direct Sybron Manufacturing, LLC	K121131 Straumann Bone Level Ø4.1 mm and Ø4.8 mm Regular Connection (RC) Roxolid Dental Implants Straumann USA	K172668 W Zirconia Implants TAV Medical Ltd.
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.	GPS® Angled Abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or completely edentulous patient. These abutments are designed to only receive a fabricated multi-unit bridge or overdenture. Abutments are intended for use in the mandible or maxilla. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Compatibility: • Legacy System: Prosthetically compatible with Zimmer Dental Tapered Screw-Vent system 3.5mm platform implants (3.7mmD, 4.1mmD, 8mm-16mm Length), 4.5mm platform implants (4.7mmD, 8mm-16mm Length), and 5.7mm platform implants (6.0mmD, 8mm-16mm Length). • SwishTapered System: Prosthetically compatible with Straumann Standard and Standard Plus system RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) and WN platform implants (4.8mmD, 6mm-12mm Length). • SwishPlus System: Prosthetically compatible with Straumann Standard and Standard Plus system RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) and WN platform implants (4.8mmD, 6mm-12mm Length). • SwishActive Implants: SwishActive implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform -3.4mm diameter) (3.5-5.0mmD, 8.5-18mm Length). • InterActive System: InterActive implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection Nobel Active™ NP (Narrow Platform-3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mmLength) implants.	Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with ·appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	TAV Medical's W Zirconia Implants are intended for surgical placement in the patient's upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading .

Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device
	Z5-BL Z-Systems AG	K132881 Z5c Z-Systems AG	K131701 Z5mlb and Z5mlc Z-Systems AG	K153509 GPS® Angled Abutment Implant Direct Sybron Manufacturing, LLC	K121131 Straumann Bone Level Ø4.1 mm and Ø4.8 mm Regular Connection (RC) Roxolid Dental Implants Straumann USA	K172668 W Zirconia Implants TAV Medical Ltd.
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	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	Overdenture abutment design	Overdenture abutment design	Bone level implant	Ti-6Al-4V alloy abutment screw used with a zirconia implant fixture
Product Codes	DZE, NHA	DZE, NHA	DZE	NHA	DZE	DZE, NHA
Features	Implants, abutments, abutment screws	Implants, abutments (abutment cemented to implant)	One-piece implants	Abutments	Implants	Implants (standard and one-piece), abutments, abutment screws
Implant Designs						
Implant Diameter, mm	4.0, 5.0	4.0, 5.0	3.6, 4.0	Not applicable	4.1, 4.8	4.1, 4.8
Implant Endosseous Length, mm	8, 10, 12	8, 10, 12	8, 10	Not applicable	8, 10, 12, 14	8, 10, 12
Platform diameter, mm	4.0, 5.0	4.0, 5.0	Not applicable	Not applicable	RC (4.1 mm)	4.8, 6.0
Implant Material	Y-TZP	Y-TZP	Y-TZP	Not applicable	TiZr alloy	Y-TZP
Implant Surface	Grit-blasted and laser modified	Grit-blasted and laser modified	Grit-blasted and laser modified	Not applicable	SLActive	Micro and macro roughened
Abutment Designs	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	Locator-type	Not provided in 510(k) Summary	Various; specifics not provided in 510(k) Summary
Prosthesis Attachment	Cement-retained; Locator-type attachment	Cement-retained	Ball-type attachment; Locator-type attachment	Locator-type	Not provided in 510(k) Summary	Not provided in 510(k) Summary
Restoration	Single-unit; Multi-unit	Single-unit; Multi-unit	Multi-unit	Multi-unit	Single-unit; Multi-unit	Single-unit; Multi-unit
Prosthetic platform diameter, mm	4.5 mm – 6.5 mm	3.6 mm	Not applicable	Locator-type	Not provided in 510(k) Summary	4.8
Abutment angle	Straight (0°), 15°	Straight (0°), 15°	Straight (0°)	15°, 30°	Not provided in 510(k) Summary	Straight (0°), 5°, 10°, 15°
Abutment material	Y-TZP	Y-TZP	Y-TZP	Titanium alloy with TiN coating	Not provided in 510(k) Summary	Ti-6Al-4V alloy
Abutment Screw Material	Y-TZP Ti-6Al-4V alloy	Not applicable	Not applicable	Not applicable	Not provided in 510(k) Summary	Ti-6Al-4V alloy
Sterilization Status/Method						
Implants	Sterile / plasma gas	Sterile / plasma gas	Sterile / plasma gas	Not applicable	Not provided in 510(k) Summary	Sterile / gamma irradiation
Abutments	Healing Cap: Sterile / plasma gas All other: Non-sterile / moist heat (steam)	Non-sterile / Dry heat	Not applicable	Non-sterile / moist heat (steam)	Not applicable	Non-sterile / moist heat (steam)
Other Components	Non-sterile / moist heat (steam)	Non-sterile / moist heat (steam)	Not applicable	Non-sterile / moist heat (steam)	Not applicable	Non-sterile / moist heat (steam)