510(k) Summary

JUL 0 3 2014

Z-Systems AG

Z5c
K132881

June 26, 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name	Z-Systems AG Bittertenstrasse 15 CH-4702 Oensingen Switzerland Telephone: +41 62 388 6969 Fax: +41 62 388 6970
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Z5c
Common Name	Dental Implant
Classification Name	Implant, endosseous, root-form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

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.

DEVICE DESCRIPTION

Z5c is a two-piece, root-form, threaded implant and abutment system made from yttria-stabilized zirconia (Y-TZP). The Z5c implant endosseous surface is grit blasted and laser modified. The Z5c implant and corresponding abutment are bonded together using a self-adhesive resin cement. The Z5c implant system is designed for single or multiple tooth restorations. Z5c implants are provided in two endosseous diameters (4.0 and 5.0 mm) and each diameter is provided in three lengths (8, 10, and 12 mm). Z5c abutments are provided in two designs, straight and angled 15°.

EQUIVALENCE TO MARKETED DEVICE

Z-Systems AG submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Z5c is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Z-Systems AG, Z-Look3 Evo SLM, K120793;
Nobel Biocare USA Inc., Nobel Biocare Endosseous Implants, K041661;
Nobel Biocare AB, Nobel Procera Zi Abutment, K091904;
Astra Tech Inc., Atlantis™ Abutment in Zirconia for Nobel Replace Implant, K091920;
Atlantis Components Inc., Atlantis™ Abutment in Zirconia for Nobel Biocare Replace, K062277;
Altatec GmbH, Camlog Implant System Modified Implants and Abutments, K083496; and
Astra Tech Inc., Atlantis™ Abutment for Camlog Implant, K110640.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject device and the predicate devices encompass the same range of physical dimensions and characteristics, including implant diameter, length, and surface treatment.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, static and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental* implants. Fatigue testing performed in a saline environment demonstrated the subject device to be equivalent to the predicate devices. Clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: a summary of clinical placement, loading, follow-up data, and multiple clinical case reports.

	Z-Systems AG Z5c	K120793	K041661	K091904	K091920	K062277	K083496	K110640
System Design	Two-piece, implant/ abutment	One-piece, implant/ abutment	Two-piece, implant/ abutment	Two-piece, implant/ abutment	Two-piece, implant/ abutment	Two-piece, implant/ abutment	Two-piece, implant/ abutment	Two-piece, implant/ abutment
Abutment Design	Straight, angled	Straight	NA	Straight	Straight, angled	Straight, angled	Straight, angled	Straight, angled
Abutment Diameter	3.6	NA	NA	3.5 - 6.0	3.5	4.3 - 6.0	3.3 - 6.0	3.3 - 6.0
Implant Diameter, mm	4.0 - 5.0	3.6 - 5.0	3.5 - 6.0	NA	NA	NA	3.3 - 6.0	NA
Implant Length, mm	8 - 12	8 - 13	8 - 16	NA	NA	NA	9 - 16	NA
Material								
Implant/ Abutment	Zirconia,	Zirconia	Titanium	Zirconia	Zirconia	Zirconia	Zirconia, Titanium	Zirconia, Titanium
Implant Surface	Grit blasted and laser modified	Grit blasted and laser modified	TiUnite®	NA	NA	NA	Grit blasted and acid etched	NA

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, Z5c has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 3, 2014

Z-Systems AG
C/O Ms. Linda K. Schulz, BSDH, RDH
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K132881
Trade/Device Name: Z5c
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 4, 2014
Received: June 5, 2014

Dear Ms. Schulz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K132881

Device Name: Z5c

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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