510(k) Summary

Z-Systems AG

Z_5mlb and Z_5mlc

June 10, 2013

SEP 05 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name	Z-Systems AG Bittertenstrasse 15 702 Oensingen Switzerland Telephone: +41 62 388 6969 Fax: +41 62 388 6970
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Representative/Consultant	Linda K. Schulz, BSDH, RDH 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: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Z_5mlb and Z_5mlc
Common Name	Dental Implant
Classification Name	Implant, endosseous, root-form
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Z_5mlb:
Z_5mlb implants are designed for surgical implantation into the edentulous upper and lower jaw for the attachment of dentures to replace missing teeth. Z_5mlb implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

Z_5mlc:
Z_5mlc implants are designed for surgical implantation into the edentulous upper and lower jaw for the attachment of dentures to replace missing teeth. Z_5mlc implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

DEVICE DESCRIPTION

The purpose of this submission is to expand the Z-Look3 Evo SLM implant line (K120793) to include two implant designs indicated for denture attachment. The Z_5mlb and Z_5mlc are one-piece, root-form, threaded implants made from yttria-stabilized zirconia (Y-TZP). Z_5mlb and Z_5mlc implants are designed for full or partial denture restorations. Z_5mlb implants are provided in two diameters (3.6 and 4.0 mm) and two endosseous lengths (8 and 10 mm).
Z_5mlc implants are provided in one diameter (4.0 mm) and one endosseous length (10 mm).

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 Z_5mlb and Z_5mlc are substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Z-Systems AG, Z-Look3 Evo SLM, K120793;

Z-Systems AG, Z-Look3 Dental Implant System, K062542;

Oral Iceberg S.L., CeraRoot Implant System, K093595;

IMTEC Corp., MDI MII 2.9 Implants, K081653;

IMTEC Corp., IMTEC Sendax MDI and MDI Plus, K031106;

Intra-Lock International, Inc., MILO™ Dental Implant System, K050970;

Implant Direct, Spectra Dental Implant System K061319; and

Ace Surgical Supply Co., Inc., Ace Surgical Secure™ Locator® 3.25 mm Implant System, K093518.

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. Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy.

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

Overall, Z_5mlb and Z_5mlc 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

September 5, 2013

Z-Systems AG
C/O Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K131701
Trade/Device Name: Z_5mlb and Z_5mlc
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 10, 2013
Received: June 11, 2013

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

Kwame Ulmer M.S.
Acting Division 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: K131701

Device Name: Z_5mlb and Z_5mlc

Z_5mlb:

Z_5mlb implants are designed for surgical implantation into the edentulous upper and lower jaw for the attachment of dentures to replace missing teeth. Z_5mlb implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

Z_5mlc:

Z_5mlc implants are designed for surgical implantation into the edentulous upper and lower jaw for the attachment of dentures to replace missing teeth. Z_5mlc implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

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)

Lauren M. Giles
2013.09.04 15:31:10 -04'00' for AIS

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131701