



Food and Drug Administration
10903 New Hampshire Avenue
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May 4, 2018

Talladium Espana, SL
% Luiz Galdino
RA/QA Specialist
Luiz Galdino
28102 Alton Way
Castaic, California 91384

Re: K162021
Trade/Device Name: 3.0 Dynamic TiBase
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 4, 2018
Received: April 4, 2018

Dear Luiz Galdino:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting 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(K162021)

Device Name

3.0 Dynamic TiBase

Indications for Use (Describe)

3.0 Dynamic TiBase are intended for use with dental implants as a support for multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Compatibility of 3.0 Dynamic TiBase®:

Implant Compatibility	Dynamic TiBase® reference	Trade Name	Implant Diameter (mm)	Abutment Post Height (mm)	Retention Type Single unit = Engaging Multi-Unit = Non-Engaging	Screw Type	Angulation	Abutment Connection
DIO®	IND30TSHRP/TIA	UF	4.0	4.0	Multi-unit	Dynamic Screw	0° to 30°	INTERNAL HEXAGON
OSSTEM®	IND30TSRNP/TIA	TS NARROW PLATFORM	3.5	3.8	Multi-unit	Dynamic Screw	0° to 20°	INTERNAL HEXAGON

All Ti-base abutments, including the designed zirconia superstructure, are intended to be manufactured and finalized by Talladium Espana.

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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Food and Drug Administration
Office of Chief Information Officer

Paperwork Reduction Act (PRA) Staff PRASStaff@fda.hhs.gov

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