March 28, 2022

Biomet 3i LLC
Krupal Patel
Principal Regulatory Specialist
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K213672
Trade/Device Name: T3 Pro Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 24, 2022
Received: February 25, 2022

Dear Krupal Patel:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213672

Device Name
T3 Pro Implants

Indications for Use *(Describe)*
The T3 Pro Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

The T3 Pro Implants may also utilize immediate loading for these indications. The T3 Pro Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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T3 Pro Implants
510(k) Summary
K213672
03/28/2022

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

I. Submitter Information:

Name: Biomet 3i LLC
Address: 4555 Riverside Drive
Palm Beach Gardens, Florida 33410
Phone: (561) 776-6923
Fax: (561) 514-6316

Contact Person: Krupal Patel
Job Title: Principal Regulatory Specialist
Email: krupal.patel@zimmerbiomet.com

II. Proprietary Trade Name: T3 Pro Implants

III. Device Classification Name: Implant, Endosseous, Root-Form (21 CFR 872.3640)

IV. Regulatory Class: Class II

V. Product Code: DZE

VI. Predicate Devices:

Primary Predicate device:

- 3i T3 Dental Implants (K122300)

Reference device:

- 3i T3 Short Implants (K150571)

VII. Product Description:

The T3 Pro Implants are basic screw-type designs available in tapered body geometry. The devices are manufactured from Commercially Pure Titanium (ASTM F67) and feature a roughened apex and traditional OSSEOTITE® coronal surface. The device is packaged in a Titanium sleeve that is inserted into a polypropylene inner tray, covered with a Tyvek lid and heat-sealed. This assembly is then placed inside a larger polyethylene thermoformed outer tray, covered with a Tyvek lid and heat-sealed. The outer tray is packaged inside a

box. The device is sold sterile. The shelf life of the T3 Pro Implants is 5 years and they are intended for single use only. The device is sterilized using gamma irradiation method. The implants are available in various platform options and feature an internal hex connection for mating with associated Biomet 3i internal connection restorative components. The implants are offered in a variety of diameters and lengths to accommodate varying patient anatomy.

VIII. Indications for Use:

The T3 Pro Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

The T3 Pro Implants may also utilize immediate loading for these indications. The T3 Pro Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

IX. Summary of the Technological Characteristics:

The T3 Pro Implant devices are identical to the predicate devices listed below in terms of operating principle and material. The subject device Indications for Use adds language for delayed and immediate loading to reflect the information that was included for the primary predicate device labeling which includes delayed and immediate loading. The technological characteristics such as implant diameters, length, connection & platform geometry, and the mating abutments are same as the predicate devices. The subject device features a tapered design with a similar screw-type design and thread form as the predicate device. Like the predicate device, T3 Pro Implant are manufactured out of commercially pure titanium per ASTM F67. The primary change from the predicate devices is implant collar and thread form. Also, T3 Pro Implant are offered in tapered design only.

A substantial equivalence comparison of subject and predicate device is provided in table below.

Table 1: Substantial equivalence table

Feature	**Subject Device** T3 Pro Dental Implants	**Primary Predicate Device** 3i T3 Dental Implants (K122300)
Intended Use/ Indications for Use	The T3 Pro Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as	Biomet 3i Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Feature	**Subject Device** T3 Pro Dental Implants	**Primary Predicate Device** 3i T3 Dental Implants (K122300)
	a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. The T3 Pro Implants may also utilize immediate loading for these indications. The T3 Pro Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	
Operating Principle	The T3 Pro Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.	The 3i T3 Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.
Fundamental Scientific Technology	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs
Material	Commercially Pure Titanium (CP4) Per ASTM F67	Commercially Pure Titanium (CP4) Per ASTM F67
Implant Body Diameter Range	Ø3.25mm, 4mm, 5mm and 6mm	Ø3.25mm, 4mm, 5mm and 6mm
Seating Platform Diameter	Ø3.4mm, 4.1mm, 5mm and 6mm	Ø3.4mm, 4.1mm, 5mm and 6mm
Implant Length	Ø3.25: 8.5mm, 10mm, 11.5mm, 13mm and 15mm Ø4.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm Ø5.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm Ø6.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm	Ø3.25: 8.5mm, 10mm, 11.5mm, 13mm, 15mm and 18mm Ø4.0: 8.5mm, 10mm, 11.5mm, 13mm, 15mm and 18mm Ø5.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm Ø6.0: 8.5mm, 10mm, 11.5mm, 13mm and 15mm
Platform Geometry	Platform Switched and Non-Platform Switched Implants	Platform Switched and Non-Platform Switched Implants
Internal External Geometry Design	Tapered only	Parallel Walled and Tapered
Implant/Abutment Mating Connection	Internal Hex	Internal Hex
Implant Collar Design	Straight Shortened Collar Design	Straight Collar Design

Feature	**Subject Device** T3 Pro Dental Implants	**Primary Predicate Device** 3i T3 Dental Implants (K122300)
Surface Finish	• Grit Blasted with Calcium Phosphate (CaP) • Dual-acid Etching (OSSEOTITE®) • Without DCD	• Grit Blasted with Calcium Phosphate (CaP) • Dual-acid Etching (OSSEOTITE®) • With or without DCD
Thread Form	Subject Tapered Implant: 23° thread & 0.8mm pitch	Predicate Tapered Implant: 35° thread & 0.8mm pitch
Anodized Platform Surface Color	Purple, Blue, Yellow and Green	Purple, Blue, Yellow and Green
Mating Components	Biomet 3i Internal Connection Restorative Components	Biomet 3i Internal Connection Restorative Components
Sterilization Method	Supplied Sterile (Gamma radiation)	Supplied Sterile (Gamma radiation)
Shelf Life	5 years	5 years
Single Use	Yes	Yes

X. Non-Clinical Testing:

The worst-case comparison for the subject devices have demonstrated substantially equivalent to K122300 with regard to mechanical performance. MR compatibility testing to support the MR conditional labeling is leveraged from K150571, where testing was conducted on the worst case cleared Biomet 3i device constructs. The subject devices do not introduce a new worst-case.

Non-clinical data submitted or relied upon to demonstrate substantial equivalence included radiation sterilization validation according to ISO 11137-1 and 11137-2, demonstration a sterility assurance level (SAL) of 10^{-6}, biological evaluation according to ISO 10993-1 demonstrating acceptable biocompatibility and accelerated and real time aging studies by reference to K122300 demonstrating a shelf life of five years.

Pyrogenicity information provided is based on FDA Guidance on "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

No clinical data were included in this submission.

XI. Conclusion:

The subject devices have demonstrated substantial equivalence to the predicate devices in that they utilize same materials and fundamental designs and also have the same intended use and principles of operation.