



Biomet 3i, LLC  
Antía Fernandez  
Regulatory Affairs Specialist  
4555 Riverside Drive  
Palm Beach Gardens, Florida 33410

June 27, 2025

Re: K251660  
Trade/Device Name: T3 Pro Implants- ZimVie Packaging System  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE  
Dated: May 30, 2025  
Received: May 30, 2025

Dear Antía Fernandez:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

*Sherrill Lathrop Blitzer*

for Andrew 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

## Indications for Use

510(k) Number (if known)

K251660

Device Name

T3 Pro Implants– ZimVie Packaging System

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

**T3 Pro Implants – ZimVie Packaging System  
K251660  
510(k) Summary  
06/26/2025**

**I. Administrative Information:**

**Manufacturer Name:** Biomet 3i LLC  
**Address:** 4555 Riverside Drive  
Palm Beach Gardens, Florida 33410  
**Phone:** (+34) 630 85 60 41

**Official Contact:** Antía Fernández

Email: [antia.fernandez@zimvie.com](mailto:antia.fernandez@zimvie.com)

- II. Trade/Proprietary Name:** T3<sup>®</sup> Pro Implant
- III. Regulation/Common Name:** Endosseous dental implant (21 CFR 872.3640)
- IV. Regulatory Class:** Class II
- V. Product Code:** DZE
- VI. Reviewing Division:** Division of Dental Devices
- VII. Predicate Devices:**  
**Primary predicate device:**
- K213672, T3<sup>®</sup> Pro Implants, Biomet 3i LLC
- Reference predicate device:**
- K122300, 3i T3<sup>®</sup> Dental Implant, Biomet 3i LLC
  - K063286, OSSEOTITE<sup>®</sup> Implants, Biomet 3i LLC
  - K082639, Tapered SwissPlus<sup>®</sup> Implants, Zimmer Dental Inc.
  - K220978, TSX<sup>®</sup> Implants, Zimmer Dental Inc.
- VIII. Indications for Use Statement:**

The T3<sup>®</sup> 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

## **Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

The T3<sup>®</sup> Pro Implants may also utilize immediate loading for these indications. The T3<sup>®</sup> 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. Subject Device Description:**

The purpose of this submission is to seek clearance of T3<sup>®</sup> Pro Implants with the new ZimVie Implant Packaging System. The material and design of the subject device is identical to the primary predicate device T3<sup>®</sup> Pro Implants cleared in K213672.

The ZimVie Implant Packaging System configuration, similarly to the primary predicate device, consists of a titanium sleeve that is inserted into a polypropylene inner tray, covered with a Tyvek lid and heat-sealed. This assembly is then placed in a heat-sealed outer tray, covered with a Tyvek<sup>®</sup> lid. The outer tray is placed inside a cardboard box, and gamma sterilized. The new ZimVie Packaging System has been standardized to align the packaging across all ZimVie implant families. The subject device in the new ZimVie Packaging System has a shelf-life of two (2) years.

### **X. Performance Data**

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- gamma irradiation sterilization validation to a sterility assurance level of  $10^{-6}$  by selecting and substantiating a 22.5 kGy to 38 kGy dose using method VDmax22.5 according to ISO 13004 and ISO 11137 (including parts 1, 2 and 3). Assessment showed that the subject device components do not create a new worst case for gamma sterilization.
- aging studies demonstrating a shelf life of two (2) years for the subject device implants, with testing of the packaging sterile barrier in accordance with ASTM F1980
- packaging studies under simulated distribution and environmental conditioning per ISTA 3A and ASTM D4169.
- biological evaluation according to ISO 10993-1 leveraged from primary predicate device demonstrating that the subject device does not introduce any increased risks or concerns regarding biocompatibility. The subject T3<sup>®</sup> Pro Implant is manufactured out of Commercially Pure Titanium conforming to ASTM F67.
- Assessment of MR Safety testing was conducted according to ASTM F2503-13 for a determination of MR Conditional on the primary predicate device, which is identical to the subject device.
- Bacterial Endotoxin Testing is routinely performed on terminally sterilized finished devices, using the Limulus Amebocyte Lysate (LAL) assay in accordance with ISO 11737-3.

## **Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

No clinical data will be included in this submission.

### **XI. Equivalence to Marketed Devices:**

The T3<sup>®</sup> Pro Implant with the new ZimVie Packaging System is identical to the primary predicate device in terms of intended use/indications for use, materials, design, operating principle, and fundamental scientific technology. The primary change is the new ZimVie Packaging System. The new packaging features a similar heat-sealed outer tray, within which the implant remains in direct contact with the same exact inner tray as cleared for the primary predicate device. The outer cardboard box and labels have been redesigned to fit the dimensions of the new outer tray. The new packaging also features the updated branding and design elements, including the ZimVie logo.

## Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System

### **XII. Conclusion:**

Any differences in the packaging system between the subject and the predicate devices do not raise any questions of safety or effectiveness. The data included in this submission demonstrates substantial equivalence to the primary predicate and reference devices listed above.

Overall, the subject device has the following similarities to the primary predicate device and the reference devices:

- same intended use,
- same operating principles,
- incorporate the same basic designs,
- incorporate the same materials, and
- have similar packaging and are sterilized using the same materials and processes.

The basis for the belief of Biomet 31 LLC that the subject device implants are substantially equivalent to the respective primary predicate and reference devices is summarized in the following Substantial Equivalence Table.

**Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

*Table 1: Substantial Equivalence Table*

<b>Features</b>	<b><u>Subject Device</u></b> T3 <sup>®</sup> Pro Implants within new ZimVie Packaging System Biomet 3i, LLC  <b>Note:</b> Biomet 3i, LLC and Zimmer Dental, Inc. have merged under the same corporate entity, ZimVie Inc. This 510(k) Premarket Notification is submitted under the entity Biomet 3i, LLC.	<b><u>Primary Predicate Device</u></b> T3 <sup>®</sup> Pro Implants (K213672) Biomet 3i, LLC	<b><u>Reference Predicate Device #1</u></b> 3i T3 <sup>®</sup> Dental Implant (K122300) Biomet 3i, LLC	<b><u>Reference Predicate Device #2</u></b> OSSEOTITE <sup>®</sup> Implants (K063286) Biomet 3i, LLC	<b><u>Reference Predicate Device #3</u></b> Zimmer Dental Tapered SwissPlus <sup>®</sup> Implants (K082639) Zimmer Dental, Inc	<b><u>Reference Predicate Device #4</u></b> TSX <sup>®</sup> Implants (K220978) Biomet 3i, LLC
<b>Intended Use</b>	Same as Primary and Reference Predicate Devices.	The purpose of Dental Implants is to replace missing individual teeth (single tooth restorations), multiple teeth, or edentulous dental arches (implant retained fixed bridge, implant-supported overdenture) by providing a means for prosthetic attachment.	The purpose of Dental Implants is to replace missing individual teeth (single tooth restorations), multiple teeth, or edentulous dental arches (implant retained fixed bridge, implant-supported overdenture) by providing a means for prosthetic attachment.	The purpose of Dental Implants is to replace missing individual teeth (single tooth restorations), multiple teeth, or edentulous dental arches (implant retained fixed bridge, implant-supported overdenture) by providing a means for prosthetic attachment.	The purpose of Dental Implants is to replace missing individual teeth (single tooth restorations), multiple teeth, or edentulous dental arches (implant retained fixed bridge, implant-supported overdenture) by providing a means for prosthetic attachment.	The purpose of Dental Implants is to replace missing individual teeth (single tooth restorations), multiple teeth, or edentulous dental arches (implant retained fixed bridge, implant-supported overdenture) by providing a means for prosthetic attachment.

**Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

<p><b>Indications for Use</b></p>	<p>Same as the Primary (K213672) and Reference (K122300, K063286) Predicate Devices.</p>	<p>T3<sup>®</sup> 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.</p> <p>T3 Pro<sup>®</sup> Implants may also utilize for immediate loading for these indications. The T3 Pro<sup>®</sup> Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal</p>	<p>Biomet 3i T3<sup>®</sup> 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.</p> <p>3i T3<sup>®</sup> Dental 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.</p>	<p>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.</p> <p>OSSEOTITE<sup>®</sup> 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.</p>	<p>The Tapered SwissPlus<sup>®</sup> Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth.</p> <p>Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.</p>	<p>The TSX<sup>®</sup> Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to minimally support the implant (minimum 1mm circumferential and 2mm apical) and provide good primary stability.</p> <p>The 3.1mmD TSX</p>
-----------------------------------	--	---	---	---	---	---

**Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

		loading, in order to restore chewing function.				Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.
<b>Operating Principle</b>	Same as Primary and Reference Predicate Devices	Biomet 3i Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at the time of placement	Biomet 3i Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at the time of placement	Biomet 3i Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at the time of placement	Zimmer Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at the time of placement.	Biomet 3i Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at the time of placement
<b>Fundamental Scientific Technology</b>	Same as Primary and Reference Predicate Devices	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs
<b>Material</b>	Same as the Primary (K2136729) and Reference (K122300, K082639) Predicate Devices.	Commercially Pure Titanium per ASTM F67	Commercially Pure Titanium per ASTM F67	Commercially Pure Titanium per ASTM F67	Commercially Pure Titanium per ASTM F67	Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136
<b>Sterilization Method</b>	Primary Predicate Device under K213672 is gamma sterilized in a similar manner, but using a different	Supplied Sterile <u>Radiation Type:</u> Gamma  <u>Minimum Dose:</u> 25 kGy	Supplied Sterile <u>Radiation Type:</u> Gamma  <u>Minimum Dose:</u> 25 kGy	Supplied Sterile <u>Radiation Type:</u> Gamma  <u>Minimum Dose:</u> 25 kGy	Supplied Sterile <u>Radiation Type:</u> Gamma  <u>Minimum Dose:</u> 22.5 kGy	Supplied Sterile <u>Radiation Type:</u> Gamma  <u>Minimum Dose:</u> 25 kGy

**Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

	<p>minimum gamma irradiation dose.</p> <p>Sterilization is performed in the same exact manner as Reference Predicate Device K082639.</p>	<p><u>Maximum Dose:</u> 38kGy</p>	<p><u>Maximum Dose:</u> 38kGy</p>	<p><u>Maximum Dose:</u> 38kGy</p>	<p><u>Maximum Dose:</u> 38kGy</p>	<p><u>Maximum Dose:</u> 38kGy</p>
<p><b>Packaging System Configuration</b></p>	<p>Subject Device uses an equivalent packaging system to the Primary (K213672), and Reference Predicate Devices (K122300, K063286). The internal protective elements including, the titanium sleeve, polypropylene inner tray, covered with a Tyvek® lid, remain unmodified from previous packaging configuration</p>	<p>Implant is packaged in a titanium sleeve, 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.</p> <p>All implants are packaged with specific accessory devices, including appropriate sized covers screws.</p> <p>The outer tray assembly and patient chart labels are placed into a cardboard box</p>	<p>Implant is packaged in a titanium sleeve, 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.</p> <p>All implants are packaged with specific accessory devices, including appropriate sized covers screws.</p> <p>The outer tray assembly and patient chart labels are placed</p>	<p>Implant is packaged in a titanium sleeve, 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.</p> <p>All implants are packaged with specific accessory devices, including appropriate sized covers screws.</p> <p>The outer tray assembly and patient chart labels are</p>	<p>Snap II Packaging System consists of a polycarbonate inner vial with a high-density polyethylene sleeve and cap, silicone o-ring, a polycarbonate outer vial with a high-density polyethylene cap, and polypropylene outer box. The implants are packaged inside the double-vial using a fixture mount. The fixture mount is assembled to the implant using the screw retention.</p>	<p>The packaging consists of an inner vial assembly (including inner vial, Titanium sleeve, implant, alignment pin, cover screw, and inner vial cap), placed into an outer vial. An outer vial receives an O-ring and the outer vial cap is torqued onto the outer vial and labeled. The outer vial assembly and patient chart labels are placed into a cardboard box and closed. A product label is applied to the outer box.</p>

**Special 510(k) Premarket Notification: T3 Pro Implants- ZimVie Packaging System**

	cleared in K213672. However, the larger PETG thermoformed outer tray, covered with a Tyvek® lid, applicable labels and outer box have been modified in order to standardize the packaging across all ZimVie implant families.	and closed. A product label is applied to the outer box.	into a cardboard box and closed. A product label is applied to the outer box.	placed into a cardboard box and closed. A product label is applied to the outer box.		
<b>Shelf Life</b>	Subject Device has a declared shelf-life of two (2) years.	5 years	5 years	5 years	5 years	5 years
<b>Single Use</b>	Same as Primary and Reference Predicate Devices	Yes	Yes	Yes	Yes	Yes