Biomet 3i LLC
Mariela Cabarcas
Sr. Regulatory Affairs Specialist
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

September 14, 2022

Re: K220978
Trade/Device Name: TSX™ Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 11, 2022
Received: August 12, 2022

Dear Mariela Cabarcas:

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)*

K220978

Device Name

TSX™ Implants

Indications for Use *(Describe)*

The TSX 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.

The 3.1mmD TSX Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

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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TSX™ Implants
510(k) Summary
09/12/2022

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:	Mariela Cabarcas
Job Title:	Sr. Regulatory Affairs Specialist
Email:	mariela.cabarcassanclemente@ZimVie.com

II. Proprietary Trade Name: TSX™ Implants

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

IV. Regulatory Class: Class II

V. Product Code: DZE

VI. Reviewing Branch: Dental Devices Branch

VII. Predicate Devices:

Primary predicate device:

- Trade Name: Tapered Screw-Vent Implant, 4.1mmD
- 510(k): K072589
- Regulation Number: 21 CFR 872.3640
- Product Code: DZE
- SE Date: 10/04/2007

Reference Device:

- Trade Name: Zimmer 3.1mmD Dental Implant System
- 510(K): K142082
- Regulation Number: 21 CFR 872.3640
- Prooduct Code: DZE, NHA

- SE: 10/28/2014

Reference Device:

- Trade Name: ScrewVent Implant; Tapered ScrewVent Implant
- 510(K): K013227
- Regulation Number: 21 CFR 872.3640
- Product Code: DZE
- SE: 11/19/2001

Reference Device:

- Trade Name: 3i T3 Dental Implants
- 510(K): K122300
- Regulation Number: 21 CFR 872.3640
- Prooduct Code: DZE
- SE: 01/30/2013

Reference Device:

- Trade Name: 3i T3 Short Implants
- 510(K): K150571
- Regulation Number: 21 CFR 872.3640
- Prooduct Code: DZE
- SE: 11/20/2015

VIII. Product Description:

TSX Dental Implants are manufactured from biocompatible titanium alloy. TSX Dental Implants surface consists of a Contemporary Hybrid Surface Treatment (Dual Acid Etch + MTX™ Textured Surface). The implants are available in different platform diameters and feature an internal hex connection for mating with associated Zimmer Dental and Biomet 3i internal connection restorative components.

For specific product descriptions, please refer to individual product labels.

TSX™ Implants:

Implant Connection	Implant Diameter (mm)	Implant Platform (mm)	Implant Length (mm)
Conical + Internal Hex	3.1	2.9	8, 10, 11.5, 13, 16
Internal Hex	3.7	3.5	8, 10, 11.5, 13, 16
	4.1	3.5	8, 10, 11.5, 13, 16
	4.7	3.5	8, 10, 11.5, 13, 16
	5.4	4.5	8, 10, 11.5, 13, 16
	6.0	4.5	8, 10, 11.5, 13, 16

NOTE: The Zimmer Dental and Biomet 3i Zirconia-based abutments have not been tested for compatibility with the TSX Implant and therefore should not be used.

IX. Indications for Use:

The TSX 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.

The 3.1mmD TSX Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

X. Summary of the Technological Characteristics:

The TSX Implants are similar to that of the predicate devices and reference devices listed below in terms of intended use, indications for use, operating principle, fundamental scientific technology, implant connection, and material. The technological characteristics such as implant diameters, length, connection and platform geometry, as well as mating abutments are similar to that of the predicate devices and reference devices, except for Zimmer Dental Zirconia-based abutments which have not been tested for compatibility with the subject devices and therefore should not be used. The subject device features a tapered design with a similar screw-type design as the predicate and reference devices. Like the Predicate Device (K072589) and Reference Devices (K013227, K142082), TSX Implants are manufactured from titanium alloy (Ti 6Al-4V ELI) per ASTM F136. The primary change from the predicate devices is the external tapered thread geometry, the hybrid surface (Dual acid-etched + MTX Surface), the new 5.4mm(D) size in 8.0, 10.0, 11.5, 13.0, and 16.0mm lengths, and the one style packaging Inner Vial for all diameters and lengths, with a Titanium sleeve based on implant size, as well as an anodized alignment pin.

The subject devices have indications for use that are similar to the predicate devices. The differences include additional information around immediate placement in extractions and natural loss of teeth. This additional language is in the indications for use for the reference devices in K142082. The intended use of the subject devices is not changed by the addition of this additional language.

A substantial equivalence comparison between the Subject Device and the Predicate and Reference Devices is provided in Table 5a below.

Table 5a: General Device Comparison					
Comparison	**Primary Predicate Device Device (K072589)**	**Reference Device #1 (K142082)**	**Reference Device #2 (K122300)**	**Reference Device #3 (K013227)**	**Subject Device**
	Tapered Screw-Vent Implant Zimmer Dental	Zimmer Eztetic, 3.1mmD Dental Implant System Zimmer Dental	3i T3 Dental Implants Biomet 3i	ScrewVent® and Tapered ScrewVent® Sulzer Dental, Incorporated (Became Zimmer Dental)	TSX Implants Biomet 3i
Indications for Use	The Tapered Screw-Vent 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.	Zimmer 3.1mmD Dental Implants are designed for use in the anterior 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. Zimmer 3.1mmD Dental 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	3i T3 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 a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. 3i T3 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.	The ScrewVent and Tapered Screw Vent Implants are intended for surgical implantation in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. In patients with an edentulous mandible, ScrewVent and Tapered ScrewVent Implants may be loaded immediately when at least four implants are placed between the metal foramina and rigidly splinted with a bar. ScrewVent® and Tapered ScrewVent® implants are	The TSX 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. The 3.1mmD TSX Implants should be splinted

Table 5a: General Device Comparison					
Comparison	**Primary Predicate Device Device (K072589)**	**Reference Device #1 (K142082)**	**Reference Device #2 (K122300)**	**Reference Device #3 (K013227)**	**Subject Device**
	Tapered Screw-Vent Implant Zimmer Dental	Zimmer Eztetic, 3.1mmD Dental Implant System Zimmer Dental	3i T3 Dental Implants Biomet 3i	ScrewVent® and Tapered ScrewVent® Sulzer Dental, Incorporated (Became Zimmer Dental)	TSX Implants Biomet 3i
		apical). The Zimmer 3.1mmD Dental Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.		placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.	to additional implants when used in the pre-molar region and should not be used in the molar region.
Operating Principle	The Tapered Screw-Vent Implant Dental Implants are placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.	The Tapered Screw-Vent Implant Dental Implants are placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.	The 3i T3 Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.	The Tapered Screw-Vent Implant Dental Implants are placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.	The TSX 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	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs	Endosseous Dental Implants; Screw-type designs
Material	Titanium Alloy (Ti-6Al-4V ELI) Per ASTM 136	Titanium Alloy (Ti-6Al-4V ELI) Per ASTM 136	Commercially Pure Titanium (CP4) Per ASTM F67	Titanium Alloy (Ti-6Al-4V ELI) Per ASTM 136	Titanium Alloy (Ti-6Al-4V ELI) Per ASTM 136

Table 5a: General Device Comparison					
Comparison	**Primary Predicate Device Device (K072589)**	**Reference Device #1 (K142082)**	**Reference Device #2 (K122300)**	**Reference Device #3 (K013227)**	**Subject Device**
	Tapered Screw-Vent Implant Zimmer Dental	Zimmer Eztetic, 3.1mmD Dental Implant System Zimmer Dental	3i T3 Dental Implants Biomet 3i	ScrewVent® and Tapered ScrewVent® Sulzer Dental, Incorporated (Became Zimmer Dental)	TSX Implants Biomet 3i
Surface Topography	Single stage surface: MTX Grit Blast using Hydroxyapatite blast media	Single stage surface: MTX Grit Blast using Hydroxyapatite blast media	Contemporary hybrid surface: Grit Blast using Hydroxyapatite blast media followed by Osseotite Dual Acid Etching	Single stage surface: MTX Grit Blast using Hydroxyapatite blast media	Contemporary hybrid surface: hybrid surface: Osseotite Dual Acid Etching surface from the coronal surface to approximately 1.5mm down the implant collar, followed by MTX Grit Blast using Hydroxyapatite blast media
Implant Body Diameter Range	4.1mm	3.1mm	3.25mm, 4.0mm, 5.0mm and 6.0mm	3.7mm, 4.7mm, 6.0mm	3.1mm, 3.7mm, 4.1mm, 4.7mm, 5.4mm (new), 6.0mm
Seating Platform Diameter	3.5mm	2.9mm	3.25mm, 4.0mm, 5mm and 6mm	3.5mm, 4.5mm, 5.7mm	2.9mm, 3.5mm, 4.5mm
Implant Length	8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm	8mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm	8.5mm, 10mm, 11.5mm, 13mm and 15.0mm	8mm, 10.0mm, 13.0mm, 16,0mm	8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
Platform Geometry	Platform switched only	Platform switched only	Platform Switched and Non-Platform Switched Implants	Platform switched only	Platform switched only
Implant External Geometry Design	Tapered only	Tapered only	Tapered / and Parallel Walled	Tapered only	Tapered only

Table 5a: General Device Comparison					
Comparison	**Primary Predicate Device Device (K072589)**	**Reference Device #1 (K142082)**	**Reference Device #2 (K122300)**	**Reference Device #3 (K013227)**	**Subject Device**
	Tapered Screw-Vent Implant Zimmer Dental	Zimmer Eztetic, 3.1mmD Dental Implant System Zimmer Dental	3i T3 Dental Implants Biomet 3i	ScrewVent® and Tapered ScrewVent® Sulzer Dental, Incorporated (Became Zimmer Dental)	TSX Implants Biomet 3i
Implant Connection	2.5, 3.0mm Hex with Friction Fit	2.1mm Hex with Friction Fit	Different implant connection	2.5, 3.0mm Hex with Friction Fit	2.1mm, 2.5mm Hex with Friction Fit
Thread Design	60° Thread Angle; 1.8mm Pitch Triple Lead Thread	60° Thread Angle; 1.2mm Pitch Triple Lead Thread	35° Thread Angle; 0.8mm Pitch Single Lead Thread	60° Thread Angle; 1.8mm Pitch Triple Lead Thread	30° Thread Angle; 1.6mm Pitch Dual Lead Thread
Restorative and Prosthetics Components	Zimmer Dental TSV Internal Connection Restorative Components	Zimmer Dental 3.1mm Eztetic Internal Connection Restorative Components	Biomet 3i Internal Connection	Zimmer Dental TSV Internal Connection Restorative Components,	Zimmer Dental TSV Internal Connection Restorative Components, except for the Zirconia-based abutments
Sterilization Method	Supplied Sterile (Gamma radiation)	Supplied Sterile (Gamma radiation)	Supplied Sterile (Gamma radiation)	Supplied Sterile (Gamma radiation)	Supplied Sterile (Gamma radiation)
Shelf Life	5 years	5 years	5 years	5 years	1 year
Single Use	Yes	Yes	Yes	Yes	Yes

XI. Non-Clinical Testing

A full ISO-Curve testing has been conducted to substantiate sufficient fatigue endurance limits for the TSX Implants for placement in the anterior and posterior regions of the mouth with compatible abutments. Testing has been performed in accordance with ISO 14801:2016 and FDA Class II Special Controls Guidance Document for Root-form Endosseous Dental Implants. 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. Hence the subject devices are labeled as MR conditional as the review of the testing is leveraged from K150571. The subject devices do not introduce a new worst-case.

Radiation sterilization validation according to ISO 11137-1 and 11137-2 was provided, demonstrating a sterility assurance level (SAL) of 10^{-6} and accelerated aging study demonstrating a shelf life of one (1) year.

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. Testing was leveraged from the reference devices in K142082 as the subject devices do not introduce a new worst-case.

Though, the LAL Bacterial Endotoxin testing determined the device meets pyrogen limit specifications, it will not be sufficient alone to demonstrate "non-pyrogenic", therefore, the subject devices will not be labeled as non-pyrogenic or pyrogen-free, nor will any claims be made in regards to non-pyrogenicity.

SEM and Energy Dispersive x-ray Spectroscopy imaging was conducted on the subject and predicate finished devices to assess the presence of residual blast media particles on the device due to the modification of the surface treatment in the subject device. The assessment conducted that the subject TSX devices presented no statistical difference compared to the predicate TSV devices and therefore are considered substantially equivalent.

Biocompatibility assessment of the final finished device per recommendations of current FDA guidance (issued on September 4, 2020) in accordance to "ISO 10993-1, Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process" has been conducted including chemical characterization, cytotoxicity and toxicological risk assessment. It is concluded that the TSX Implants are substantially equivalent to the predicate devices in terms of biocompatibility inclusive of base materials, manufacturing processes inclusive of surface treatments.

No clinical data were included in this submission.

XII. Conclusion:

The subject device has demonstrated substantial equivalence to the predicate devices in that it has the same intended use, the same operating principle, identical materials and similar fundamental design.