October 23, 2024

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

Re: K241753
Trade/Device Name: Immediate Molar Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: June 18, 2024
Received: September 19, 2024

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 (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

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

INDICATIONS FOR USE

510(k) Number: K241753

Device Name: Immediate Molar Implants

Indications for Use:
Immediate Molar 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 loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Immediate Molar Dental Implants may also utilize immediate loading for these indications. Immediate Molar 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 Immediate Molar Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to provide good primary stability. The Immediate Molar Dental Implants are intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications.

The Immediate Molar Dental Implants are also indicated for compatibility with the following OEM abutment systems:

Abutment System Name	Models	Platform Diameters
Abutments manufactured by Terrats Medical SL	Titanium Abutments	4.1, 5.0 and 5.7mm
Abutments manufactured by Zfx GmbH	Titanium Abutments	4.1, 5.0 and 5.7mm

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 OF NEEDED)

Concurrence of CDRH, Office of Product Evaluation and Quality (OPEQ)

Immediate Molar Implants
510(k) Summary
21 CFR 807.92
23-Oct-2024

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

II. Proprietary Trade Name: Immediate Molar 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:

- T3 PRO Implants (K213672)

Reference Predicate Devices:

- TSX Implants (K220978)
- Tapered Screw Vent Implants (K013227)
- 3i T3 Short Dental Implants (K150571)
- Implanova (K210523)
- Southern Implants MAX Implant System (K191054)

VII. Product Description:

The Immediate Molar 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 Immediate Molar 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 and also a TSV connection for mating with associated Zimmer Dental TSV connection restorative components. The implants are also compatible with titanium abutments manufactured by Terrats Medical SL and Zfx GmbH. The implants are offered in a variety of diameters and lengths to accommodate varying patient anatomy. The T3 PRO Immediate Molar Implants are offered in 8, 10 and 11.5mm implant lengths for each of the implant body diameter sizes of 7, 8 and 9mm. The TSX Immediate Molar Implants are offered in 6, 8, 10 and 11.5mm implant lengths for each of the implant body diameter sizes of 7 and 8mm. The TSX Immediate Molar Implants are offered in 8, 10 and 11.5mm lengths for implant body diameter size of 9mm.

VIII. Indications for Use:

Immediate Molar 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 loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Immediate Molar Dental Implants may also utilize immediate loading for these indications. Immediate Molar 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 Immediate Molar Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to provide good primary stability. The Immediate Molar Dental Implants are intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications.

The Immediate Molar Dental Implants are also indicated for compatibility with the following OEM abutment systems:

Abutment System Name	Models	Platform Diameters
Abutments manufactured by Terrats Medical SL	Titanium Abutments	4.1, 5.0 and 5.7mm
Abutments manufactured by Zfx GmbH	Titanium Abutments	4.1, 5.0 and 5.7mm

IX. Summary of the Technological Characteristics:

The Immediate Molar 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 immediate implant placement to reflect the information that was included for the reference predicate device labeling which includes immediate implant placement. The technological characteristics such as length, connection & platform geometry, and the mating abutments are identical 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 primary predicate device, Immediate Molar Implant are manufactured out of commercially pure titanium per ASTM F67. The primary change from the predicate devices is implant diameter and thread form. Also, Immediate Molar Implant are offered in platform switched design only.

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

Table 1: Substantial equivalence table

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
Intended Use/ Indications for Use	Immediate Molar 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 loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. Immediate Molar Dental Implants may also utilize immediate loading for these indications. Immediate Molar Dental Implants are intended for immediate function	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 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	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 Tapered Screw-Vent and Screw-Vent Implants are intended for surgical implantation in 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.	The 3i T3 Short 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 Implanova® implants are intended for endosseous implantation in the mandible and maxilla for use as an artificial root structure. These root form implants can be used to replace single or multiple teeth missing teeth and/or to support a fixed or removable prosthesis in partially or completely edentulous upper and lower dental arches. Implanova® All-in-One™ implants are indicated to be used when primary stability of the implant allows presence of an abutment at the time of placement. Implanova® All-in-one™ are	Southern Implants MAX implant is intended for implantation in maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
	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 Immediate Molar Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to provide good primary stability. The Immediate Molar Dental Implants are intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the	appropriate occlusal loading, in order to restore chewing function.	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.			immediately loaded by the presence of the abutment, but the occlusal forces need to be controlled and restricted while osseointegration takes place.	single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
	placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. The Immediate Molar Dental Implants are also compatible with titanium abutments manufactured by Terrats Medical S.L. and Zfx GmbH						
Operating Principle	The Immediate Molar Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.	The T3 Pro Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.	The TSX Dental Implants achieve their intended purpose based upon their macro design features, which maximize primary stability at time of placement.	The Tapered Screw Vent 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 Short Dental Implants are placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.	The Implanova Dental Implants are placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.	The Southern Max Dental Implants are placed into a prepared osteotomy and once stability is achieved, the implant is restored with a compatible restorative device.

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
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	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	Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136	Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136	Commercially Pure Titanium (CP4) Per ASTM F67	Titanium Alloy (ASTM F136)	Commercially Pure Titanium (CP4) Per ASTM F67
Implant Body Diameter Range	Ø7.0mm, 8.0mm, and 9.0mm	Ø3.25mm, 4mm, 5.0mm and 6.0mm	Ø3.1mm, 3.7mm, 4.1mm, 4.7mm, 5.4mm and 6.0mm	Ø3.7mm, 4.7mm and 6.0mm	Ø5.0mm and 6.0mm	Ø6.5, 7.5 and 8.5mm	Ø6.0mm, 7.0mm, 8.0mm and 9.0mm
Seating Platform Diameter	Subject T3 PRO Immediate Molar Implant: Ø6.0mm Subject TSX Immediate Molar Implant: Ø5.7mm	Ø3.4mm, 4.1mm, 5.0mm and 6.0mm	Ø2.9mm, 3.5mm and 4.5mm	Ø3.5mm, 4.5mm and 5.7mm	Ø5.0mm and 6.0mm	Ø6.5mm	Ø4.5mm, 5.5mm, 5.7mm, 6.5mm and 7.5mm
Implant Length	Subject T3 PRO Immediate Molar Implant: 8.0mm, 10.0mm and 11.5mm Subject TSX Immediate Molar	8.5mm, 10mm, 11.5mm, 13.0mm and 15mm	8.0mm, 10mm, 11.5mm, 13.0mm and 16mm	8.0mm, 10.0mm, 13.0mm and 16.0mm	5.0mm and 6.0mm	6.0mm, 8.0mm and 10.0mm	6.0mm, 7.0mm, 9.0mm and 11.0mm

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
	Implant: 6.0mm, 8.0mm, 10mm, and 11.5mm (Note: 6.0mm length option is not available for the 9mmD diameter option of TSX Immediate Molar Implants)						
Platform Geometry	Platform Switched only	Platform Switched and Non-Platform Switched Implants	Platform Switched only	Platform Switched only	Non-Platform Switched Implants	Platform Switched only	Platform Switched only
Internal External Geometry Design	Tapered only	Tapered only	Tapered only	Tapered only	Parallel Walled only	Tapered only	Tapered only
Implant Connection	Subject T3 PRO Immediate Molar Implant: Biomet 3i Internal Hex (Certain® Connection) Subject TSX Immediate Molar	Biomet 3i Internal Hex (Certain® Connection)	2.1mm, 2.5mm Hex with Friction Fit	2.5mm, 3.0mm Hex with Friction Fit	External Hex	Internal Hexagon	External Hex Tri-lobe Internal Hex

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
	Implant: 3.0mm Hex with Friction Fit						
Surface Finish	• Grit Blasted with Calcium Phosphate (CaP) • Dual-acid Etching (OSSEOTITE®)	• Grit Blasted with Calcium Phosphate (CaP) • Dual-acid Etching (OSSEOTITE®)	Contemporary 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.	Single stage surface: MTX Grit Blast using Hydroxyapatite blast media	• Grit Blasted with Calcium Phosphate (CaP) • Dual-acid Etching (OSSEOTITE®)	Resorbable Blast Texture Media (Calcium Phosphate)	Grit-blasted
Anodized Platform Surface Color	Subject T3 PRO Immediate Molar Implant: Green Subject TSX Immediate Molar Implant: None	Purple, Blue, Yellow and Green	None	None	Yellow and Green	None	None
Mating Components	Subject T3 PRO Immediate Molar Implant:	Biomet 3i Internal Hex Connection Restorative Components	Zimmer Dental TSV Internal Connection Restorative Components, except	Zimmer Dental TSV Internal Connection Restorative Components	Biomet 3i External Hex Connection Restorative Components	Straight type abutments, straight type abutment screws and straight type	Southern Implants Restorative Components with external hex, tri-lobe

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
	Biomet 3i Internal Hex Connection Restorative Components (Compatible with 4.1mm, 5.0mm and 6.0mm connection); and titanium abutments manufactured by Terrats Medical SL and Zfx GmbH. Subject TSX Immediate Molar Implant: Zimmer Dental TSV Internal Connection Restorative Components (Compatible with 5.7mm connection); and titanium abutments manufactured by Terrats Medical SL and Zfx GmbH.		for the Zirconia based abutments			temporary abutments that are intended to be on Astra Tech's OsseoSpeed™ TX 3.5S and OsseoSpeed™ TX 4.0S implant fixtures.	and internal hex interface

Feature	**Subject Device** Immediate Molar Dental Implants	**Primary Predicate Device** T3 PRO Dental Implants (K213672)	**Reference Predicate Device** TSX Dental Implants (K220978)	**Reference Predicate Device** TSV Dental Implants (K013227)	**Reference Predicate Device** 3i T3 Short Dental Implants (K150571)	**Reference Predicate Device** Implanova (K210523)	**Reference Predicate Device** Southern Implants MAX Implant System (K191054)
Sterilization Method	Supplied Sterile (Gamma radiation)	Supplied Sterile (Gamma radiation)	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	5 years	5 years	5 years
Single Use	Yes	Yes	Yes	Yes	Yes	Yes	Yes

X. Non-Clinical Testing:

The worst-case comparison for the subject devices have demonstrated substantially equivalent to K213672 and K220978 with regard to fatigue 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. Pull out tests and surface area analyses of the short implants (i.e. implants with implantable thread length less than 7mm) demonstrated that the subject device is substantially equivalent to the reference device T3 Shorts (K150571). The Immediate Molar Implants possess the same multi-level surface topography by reference to K213672, which consist of surface treatments in the form of grit blasting with Calcium Phosphate (CaP) media per ASTM F1185 followed by the well-established dual acid etching process. 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 K213672 demonstrating a shelf life of five years.

There is a contractual agreement with Terrats Medical SL to support compatibility of Immediate Molar Implants for use with their Titanium abutments, without needing reverse engineering analysis testing. Zfx GmbH is a wholly owned subsidiary of ZimVie, which is also the parent company of Biomet 3i LLC. Engineering drawings are shared between Biomet 3i LLC and Zfx GmbH to support compatibility of Immediate Molar Implants for use with their Titanium abutments, without needing reverse engineering analysis testing.

The subject devices will not be labeled as non-pyrogenic or pyrogen-free, nor will any claims be made in regards to non-pyrogenicity.

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.