



Ditron Dental LTD
Tali Hazan
RA Consultant
M.P Upper Galilee
Ramot-Naftali, 1383000
ISRAEL

April 30, 2024

Re: K233231
Trade/Device Name: Dental Implants and Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 29, 2024
Received: April 1, 2024

Dear Tali Hazan:

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.

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
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K233231

Device Name
Dental Implants and Abutments

Indications for Use (Describe)

Ditron's Dental Implants and Abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

- Two stage: MPI, ULT, API and CPI models
- One stage: OPI and TPI models

The 3.3 and 3.0mm diameter models for One stage OPI and TPI, Two stage MPI, Two stage and API implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.

Two stage and One stage implants for temporary or long-term use: MPI, ULT, API, CPI, OPI and TPI are self-tapping Titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis and protection of graft sites.

MPI, ULT, API, CPI, OPI and TPI designs are indicated for immediate loading (except for MPI and API in 6.0mm length) when good primary stability is achieved and with appropriate occlusal loading.

MPI, ULT, API, CPI, OPI and TPI are indicated for immediate loading (except for MPI and API in 6.0mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading.

The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.

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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510(k) Summary for Ditron's Dental Implants and Abutments

Date Prepared: April 25, 2024

1. Submitter

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2. Device

Common or usual name: Dental Implants and Abutments
Proprietary/Trade name: Dental Implants and Abutments
Implants subtypes: TPI – Tissue Level (One Piece) Precision Implant
Classification name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Product Code: Primary: DZE, Secondary: NHA

3. Predicate Device

The devices within this submission are substantially equivalent to the following predicate/reference devices:

- **Primary Predicate Device:** Ditron Precision Ltd's legally marketed Dental Implants and Abutments, cleared under 510(k) number K140728.
- **Reference Device:** Ditron Precision Ltd's legally marketed Dental Implants and Abutments, cleared under 510(k) number K161497.
- **Reference Device:** TRI Dental Implants' legally marketed TRI-matrix® Tissue-Level implant, cleared under K203660.

4. Device Description:

This submission covers changes related to Ditron's Dental implants and abutments. The inclusion of additional product variations aims to provide dental surgeons with a broader range of implant and abutment options for patient treatment.

The requested additions to Ditron's Dental Implants and Abutments within this 510(k) are hereby described:

- **An additional implant type: TPI (Tissue Level (One Piece) Precision Implant) –**
The TPI design is based on Ditron's cleared MPI Implant model and the 3.0mm Straight Multi-Unit Abutment, creating a one-piece implant. The TPI's implant part is identical to the cleared MPI Implant model, and the 3.0mm MPI Straight Multi-unit part has minor dimensional modifications and color anodization for aesthetic purposes. The TPI compatible Cover and Prosthetic Screws are color anodized as well.
- **An additional Abutment type: TPI Healing Caps Abutment –**
The TPI Healing Caps design is based on Ditron's cleared Cylindered Healing Caps. The TPI Healing Caps are color-anodized for aesthetic purposes. The TPI Healing Caps Abutments are available in several Gingival height dimensions of 3.5, 4.5 and 5.5mm.
- **Modification to Cleared Titanium Abutments –** Addition of color anodization as an option for all of the Ditron Dental System Titanium Alloy Grade 23 (Ti 6Al-4V ELI) Abutments cleared under K140727 and K161497, to enhance the aesthetic outcome of the dental prosthetics.
- **An additional Abutment type: TPI Titanium Coping Abutments –** The TPI Titanium Coping Abutment design is based on Ditron's cleared Temporary Abutment. The TPI Titanium Coping Abutments are directly connected to the endosseous dental implant and are intended to provide a basis for prosthetic restoration of single (Crown) or multiple teeth (Bridge). The TPI Titanium Coping Abutment is available in several lengths and restoration options: 11.0mm Bridge, 11.0 Crown, 4.5mm Bridge, 4.5mm Crown.
- **An additional Abutment type: TPI Overdenture Liberator Abutment –** The TPI Overdenture Liberator Abutment design is based on Ditron's cleared Liberator Abutment. The Liberator Abutment is available in several length dimensions of 2.0, 3.0, 4.0 and 5.0mm.

5. Indications for Use:

Ditron's Dental Implants and Abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

- Two stage: MPI, ULT, API and CPI models
- One stage: OPI and TPI models

The 3.3 and 3.0mm diameter models for One stage OPI and TPI, Two stage MPI, Two stage and API implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.

Two stage and One stage implants for temporary or long-term use: MPI, ULT, API, CPI, OPI and TPI are self-tapping Titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis and protection of graft sites.

MPI, ULT, API, CPI, OPI and TPI designs are indicated for immediate loading (except for MPI and API in 6.0mm length) when good primary stability is achieved and with appropriate occlusal loading.

MPI, ULT, API, CPI, OPI and TPI are indicated for immediate loading (except for MPI and API in 6.0mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading.

The 30° multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration.

The 17° multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.

6. Technological Characteristics and Substantial Equivalence:

The subjected devices are substantially equivalent to Ditron's Dental Implants and Abutments that were cleared under K140728 and K161497, and with TRI Dental Implants' TRI-matrix® Tissue-Level implant cleared under K203660, as identified above under the 'predicate devices' section.

The indications for use are identical between the primary predicate and subject device indications for use statement, except for the addition of the TPI model. The additional TPI dental implants and abutments and Ditron's cleared predicate devices have the same indications for use, same shape, design and characteristics. The only characteristics that are not covered by the Ditron cleared predicates is the color anodization of the tissue level part of subject implant and abutments. This characteristic is equivalent to the TRI-matrix® Tissue-Level implant. All of the changes that differentiate the additional TPI dental implants and abutments from the predicate devices were addressed and evaluated.

Table 1: Substantial Equivalence Table - Intended use

<p align="center">- Subject Device - TPI Implant</p>	<p align="center">- Primary Predicate Device - Ditron's Dental Implants and Abutments [MPI, OPI and Multi-Unit Abutment] Cleared under K140728</p>	<p align="center">- Reference Device - Ditron's Dental Implants and Abutments [MPI L6.0mm and Liberator] Cleared under K161497</p>	<p align="center">- Reference Device - TRI Dental Implants' TRI-matrix® Implant Line [TRI-matrix® Tissue-Level] Cleared under K203660</p>	<p align="center">Substantial Equivalence Discussion</p>
<p>Ditron's Dental Implants and Abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.</p> <ul style="list-style-type: none"> • Two stage: MPI, ULT, API and CPI models • One stage: OPI and TPI models <p>The 3.3 and 3.0mm diameter models for One stage OPI and TPI, Two stage MPI, Two stage and API implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.</p> <p>Two stage and One stage implants for temporary or long-term use: MPI, ULT, API, CPI, OPI, and TPI are self-tapping Titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown,</p>	<p>Ditron's Dental Implants and Abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.</p> <ul style="list-style-type: none"> • Two stage: MPI, and CPI models • One stage: OPI model <p>One stage and One piece OPI 3.3 and 3.0 mm diameter implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants. Two stage and One stage implants for temporary or long-term use: MPI, CPI, OPI are self-tapping Titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis and protection of graft sites.</p>	<p>Ditron's Dental Implants and Abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.</p> <ul style="list-style-type: none"> • Two stage: MPI, ULT, API and CPI models • One stage: OPI model <p>The 3.3 and 3.0mm diameter models for One stage OPI, Two stage MPI, Two stage and API implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.</p> <p>Two stage and One stage implants for temporary or long-term use: MPI, ULT, API, CPI, OPI are self-tapping Titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis and protection of graft sites.</p>	<p>The TRI-matrix® Implant Line is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients.</p> <p>TRI-matrix® Implant Line allows for one and two stage surgical procedures. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI-matrix® Implant Line 6.5 mm implants are intended for delayed loading only.</p> <p>The TRI-matrix® Crown Abutment is intended for</p>	<p>Same.</p> <p>All predicate devices (primary and references), have the same indications for use. The MPI length dimensions greater than 6.0mm, multi-unit abutments, and the One-Piece design concept were leveraged from 510(k) K140728 and the 6.0mm lengths of the TPI together with the modified Liberator, were leveraged from</p>

- Subject Device - TPI Implant	- Primary Predicate Device - Ditron's Dental Implants and Abutments [MPI, OPI and Multi-Unit Abutment] Cleared under K140728	- Reference Device - Ditron's Dental Implants and Abutments [MPI L6.0mm and Liberator] Cleared under K161497	- Reference Device - TRI Dental Implants' TRI-matrix® Implant Line [TRI-matrix® Tissue-Level] Cleared under K203660	Substantial Equivalence Discussion
<p>bridge and prosthesis and protection of graft sites. MPI, ULT, API, CPI, OPI and TPI designs are indicated for immediate loading (except for MPI and API in 6.0mm length) when good primary stability is achieved and with appropriate occlusal loading. MPI, ULT, API, CPI, OPI and TPI are indicated for immediate loading (except for MPI and API in 6.0mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading. The 30° multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17° multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.</p>	<p>MPI, CPI, and OPI designs are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. MPI, CPI and OPI are indicated for immediate loading in single tooth restorations when good primary stability is achieved with appropriate occlusal loading. The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.</p>	<p>MPI, ULT, API, CPI and OPI designs are indicated for immediate loading (except for MPI and API in 6.0mm length) when good primary stability is achieved and with appropriate occlusal loading. MPI, ULT, API, CPI and OPI are indicated for immediate loading (except for MPI and API in 6.0mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading. The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.</p>	<p>use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the TRI-matrix® Crown Abutment to the endosseous implant.</p>	<p>510(k) K161497 for the addition TPI model. The TRI reference device includes a crown that is not part of the subject device and therefore not applicable.</p>

Table 2: Table of Substantial Equivalence – Technological Characteristics - TPI Implants

Feature	- Subject Device - TPI Implant	Primary Predicate Device - Ditron's Dental Implants and Abutments [MPI, OPI and Multi-Unit Abutment] Cleared under K140728	Reference Device -Ditron's Dental Implants and Abutments [MPI L6.0mm and Liberator] Cleared under K161497	Reference Device - TRI Dental Implants' TRI-matrix® Implant Line [TRI-matrix® Tissue-Level] Cleared under K203660	Substantial Equivalence Discussion
Material	Ti-6Al-4V-ELI	Ti-6Al-4V-ELI	Ti-6Al-4V-ELI	Ti-6Al-4V-ELI	Identical to all compared devices.
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous and partially edentulous individuals	Identical to all compared devices.
Placement method	Placing the implant immediately after drilling	Placing the implant immediately after drilling	Placing the implant immediately after drilling	Placing the implant immediately after drilling (when a one-stage surgical procedure is applied)	Identical to K140728 and K161497.
Maximum Abutment Angle	0°	MPI: 0° - 30° OPI: 0°	30° for all implants except for: Implants with L=6.0mm: straight abutment only, and; Implants with OD of less than 3.75mm: Up to 25° Abutments only.	N/A since the reference device is used only for the tissue level surface treatment (Color anodization) comparison.	Similar. All angles are within the cleared range.
Construction	Machined	Machined	Machined	Machined	Identical to all compared devices.
Surface Treatment	<ul style="list-style-type: none"> Sand alumina large grit blasting and Acid etching Color using anodization (Blue, Yellow-gold, Pink-Purple and Green) of 	<ul style="list-style-type: none"> Implants (OPI & MPI): Sand alumina large grit blasting and Acid etching Multi-Unit: None. 	<ul style="list-style-type: none"> MPI: Sand alumina large grit blasting and Acid etching. 	<ul style="list-style-type: none"> Sand alumina large grit blasting and Acid etching. Color using anodization (Pink-Purple and Green) of the tissue level implant neck portion (collar). 	Similar. The color anodization of the tissue level (neck portion) of the implant is similar to the reference TRI implant. The surface SLA treatment is identical to K140728 and K161497, except for the anodization colors. This difference in color does not lead

Feature	- Subject Device - TPI Implant	Primary Predicate Device - Ditron's Dental Implants and Abutments [MPI, OPI and Multi-Unit Abutment] Cleared under K140728	Reference Device -Ditron's Dental Implants and Abutments [MPI L6.0mm and Liberator] Cleared under K161497	Reference Device - TRI Dental Implants' TRI-matrix® Implant Line [TRI-matrix® Tissue-Level] Cleared under K203660	Substantial Equivalence Discussion
	the tissue level implant neck portion.				to new questions of safety and effectiveness.
Implant to Abutment Connection	<u>One-Piece Implant</u> , in which the endosseous and abutment portions consist of one unit.	OPI: <u>One-Piece implant</u> , in which the endosseous and abutment portions consist of one unit. MPI: Ditron Dental Internal Hexagon	Ditron Dental Internal Hexagon	N/A since the reference device is used only for the tissue level surface treatment comparison	Similar, since Ditron's cleared OPI implant includes the same one-piece concept where the implant and abutment are integrated.
Implant Design	<u>One-piece design</u> with tapered body (MPI design integrated with straight multi-unit abutment)	<ul style="list-style-type: none"> OPI: <u>One-Piece design</u> with tapered body MPI: Two-piece model design (implant and abutments including angled multi-unit abutment), with tapered body 	Two-piece MPI model design (short implant and abutments including straight multi-unit abutment), with Tapered body	N/A since the reference device is used only for the tissue level surface treatment comparison	<p>Similar.</p> <ul style="list-style-type: none"> Ditron's cleared OPI implant includes the one-piece design with tapered body. The TPI utilizes the same design as the MPI when connected to a straight multi-unit, serving as a one-piece implant. Therefore, it is fully covered under the existing design of Ditron's implant models.
Interface Type	Engaging	All: Engaging Multi-Unit only: non-Engaging	Engaging	N/A since the reference device is used only for the tissue level surface treatment comparison	Identical to all engaging devices in K140728 and K161497.
Prosthetic Platforms	Straight TPI prosthetic platform (<i>Also referred to as "Connection Platform Cone"</i>): external hexalobular	Multi-Unit abutment platform (angulated): external hexagon	Multi-Unit abutment platform (Straight): external hexagon	N/A since the reference device is used only for the tissue level surface treatment comparison	Similar. No new questions of safety and effectiveness.

Feature	- Subject Device - TPI Implant	Primary Predicate Device - Ditron's Dental Implants and Abutments [MPI, OPI and Multi-Unit Abutment] Cleared under K140728	Reference Device -Ditron's Dental Implants and Abutments [MPI L6.0mm and Liberator] Cleared under K161497	Reference Device - TRI Dental Implants' TRI-matrix® Implant Line [TRI-matrix® Tissue-Level] Cleared under K203660	Substantial Equivalence Discussion
Implant Diameter and Length Dimensions (mm)	Ø3.3, Ø3.5 and Ø3.75mm for lengths of L8.0, 10, 11.5, 13 and 16mm <i>And;</i> Ø4.2 and Ø5.0mm for lengths of: L6.0, 8.0, 10, 11.5, 13, 16mm.	MPI: Ø3.5mm, 3.75 mm, 4.2 mm, 5.0 mm and 6.0 mm for Lengths of: 8.0, 10, 11.5, 13 and 16 mm for Lengths of: 8.0, 10, 11.5, 13 and 16mm. OPI: Ø3.0 and 3.3mm for Lengths of: L8.0, 10, 11.5, 13 and 16mm.	MPI: OD=3.3mm for Lengths of: L8.0, 10.0, 11.5. 13 and 16mm. OD=4.2, 5.0. 6.0 for L=6.0mm.	N/A since the reference device is used only for the tissue level surface treatment comparison	Similar. Dimensions fall under existing range of dimensions.
Abutment Diameter	TPI Implant Tissue level element: Ø4.8mm (refers to the integrated straight multi-unit abutment portion)	N/A. Since there is no straight multi-unit abutment.	Ø4.8mm (Straight multi-unit individual abutment)	N/A since the reference device is used only for the tissue level surface treatment comparison	Identical to K161497
Gingival Height(s)	3.0mm	N/A. Since there is no straight multi-unit abutment.	N/A. Ø1.0, 2.0, 3.0, 4.0, and 5.0mm (individual straight multi-unit abutment)	Gingival Heights, mm 1.8 mm	Identical to K161497 since dimensions fall within the range of the cleared straight multi-unit, which is integrated in the TPI subject device.
Shelf-life	5 Years	5 Years	5 Years	5 Years	Identical to all compared devices.
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Identical to all compared devices.
Single use	Yes	Yes	Yes	Yes	Identical to all compared devices.

Table 3: Table of Substantial Equivalence – Technological Characteristics - Abutments

Note: This part of the substantial equivalence table, summarizes the technological characteristics of the various abutments, and is divided to the mutual aspects relevant to all Ditron’s abutments which are applicable to the TPI implant and its associated abutments, followed by each variation, identified and addressed by individually by its own, as follows:

Feature	All Subject Abutments	- Primary Predicate Device - Ditron’s Dental Implants and Abutments [Multi-Unit Abutment] Cleared under K140728	- Reference Device - Ditron's Dental Implants and Abutments [Liberator] Cleared under K161497	- Reference Device - TRI Dental Implants’ TRI-matrix® Implant Line [TRI-matrix® Tissue-Level, Abutment Screws] Cleared under K203660	Substantial Equivalence Discussion
Indications for Use	As specified in Table 1 for each device (subject device, predicate device and reference device), since the indications for use statement refers to both implants and abutments as an integral system.				Identical to all compared devices.
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous and partially edentulous individuals	Identical to all compared devices.
Construction	Machined with or without anodization	Machined	Machined	Machined with or without anodization	Similar to all compared devices
Material	Ti-6Al-4V-ELI	Ti-6Al-4V-ELI	Ti-6Al-4V-ELI	Ti-6Al-4V-ELI	Identical to all compared devices.
Surface Treatment	Healing Caps, Prosthetic and Cover Screws and optional for all Ditron titanium abutments: Color Anodization (Blue, Yellow-gold, Pink-Purple and Green)	Multi-Unit abutment: none	Liberator: None	Implant: Pink anodized collar (Tissue Level) Abutment Screws: Gold anodized	Similar. The anodization of TRI’s reference device abutment’s tissue level (neck portion) of the implant and the Abutment Screws is similar to the subject device.

Feature	All Subject Abutments	- Primary Predicate Device - Ditron's Dental Implants and Abutments [Multi-Unit Abutment] Cleared under K140728	- Reference Device - Ditron's Dental Implants and Abutments [Liberator] Cleared under K161497	- Reference Device - TRI Dental Implants' TRI- matrix® Implant Line [TRI- matrix® Tissue-Level, Abutment Screws] Cleared under K203660	Substantial Equivalence Discussion
Sterilization Method	Cover Screws: Gamma Irradiation Other abutments: Non-Sterile Provided	Cover Screws: Gamma Irradiation Other abutments: Non-sterile provided	Cover Screws: Gamma Irradiation Other abutments: Non-Sterile Provided	Implant: Gamma Irradiation Abutment Screws: Non-Sterile Provided	Identical to all compared devices.
End-User Sterilization	Cover Screws: Sterile Provided Other abutments: Moist steam sterilization	Cover Screws: Sterile Provided Other abutments: Moist steam sterilization	Cover Screws: Sterile Provided Other abutments: Moist steam sterilization	Implants: Sterile Provided Abutment Screws: Moist steam sterilization	Identical to all compared devices.
Packaging	Cover Screws: Packaged with implant. Other abutments: Prosthetic Pouch	Cover Screws: Packaged with implant. Other abutments: Prosthetic Pouch	Cover Screws: Packaged with implant. Other abutments: Prosthetic Pouch	N/A since the reference device is used only for the tissue level surface treatment comparison	identical to K140728 and K161497
Single use	Yes	Yes	Yes	Yes	Identical to all compared devices.

Table 4: Table of Substantial Equivalence – Technological Characteristics - TPI Healing Cap

Feature	TPI Healing Cap Subject Device	MPI Healing Cap Predicate Device cleared under K140728	Substantial Equivalence Discussion
Healing Cap Diameter	4.8mm	4.8mm	Identical to K140728
Healing Cap Height	3.5, 4.5, 5.5mm	4.5mm	Similar. The subject device includes additional height dimensions which do not lead to new questions of safety and effectiveness.
Duration	180 Days	180 Days	Identical to K140728
Shape	Cylindrical	Cylindrical	Identical to K140728
Abutment Connection	Straight TPI prosthetic platform: external hexalobular	Ditron Dental Multi-Unit Abutments: external hexagon	Similar. Minor differences in connection platform. This change does not lead to new questions of safety and effectiveness, since the predicate device's connection has a similar shape. Yet, the subject device adds a more robust design due to the additional hexalobular design (as elaborated in Table 2).

Table 5: Table of Substantial Equivalence – Technological Characteristics - TPI Titanium Copings

Feature	TPI Titanium Copings Abutment Subject Device	Temporary Titanium Abutments Predicate Device cleared under K140728	Substantial Equivalence Discussion
Connection	Coping Abutment Bridges: Non-Engaging. Coping Abutment Crowns: Engaging	Non-Engaging	Similar. No new questions of safety and effectiveness
Diameter	4.8mm	4.8mm	Identical to K140728
Height	Short Version L4.85mm Long Version L11.0mm	12.0mm	Similar. Slight difference in height that do not lead to new questions of safety and effectiveness
Shape	Cylindrical with retention grooves	Cylindrical with retention grooves	Identical to K140728
Abutment Connection	Straight TPI prosthetic platform: External hexalobular	Ditron Dental Multi-Unit Abutments platform: External Hexagon	Similar. Minor differences in connection platform. This change does not lead to new questions of safety and effectiveness, since the predicate device's connection has a similar

Feature	TPI Titanium Copings Abutment Subject Device	Temporary Titanium Abutments Predicate Device cleared under K140728	Substantial Equivalence Discussion
			shape. Yet, the subject device adds a more robust design due to the additional hexalobular design (as elaborated in Table 2).
Angulation	0°	0°	Identical to K140728

Table 6: Table of Substantial Equivalence – Technological Characteristics - TPI Liberator Abutments

Feature	TPI Liberator Abutments Subject Device	Liberator Abutments Reference Device cleared under K161497	Substantial Equivalence Discussion
Height	3.5, 4.5, 5.5mm	2.35, 3.35, 4.35, 5.35, 6.35mm	All dimensions are within the range of the cleared device.
Shape	Cylindrical abutments for overdentures attachment system	Cylindrical abutments for overdentures attachment system	Identical to K140728
Surface Treatment	None	None	Identical to K140728
Abutment Connection	Straight TPI prosthetic platform with external hexalobular	Ditron Dental Straight Multi-Unit Abutments platform: external Hexagon	Minor differences in connection platform that do not lead to new questions of safety and effectiveness
Angulation	0°	0°	Identical to K161497

7. Non-clinical Performance Data:

The following non-clinical tests were performed in order to demonstrate the substantial equivalence of the additional TPI Dental Implants and Abutments:

- Biocompatibility:** Biocompatibility evaluation and testing according to ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* and ISO 10993-11 *Biological evaluation of medical devices Part 11: Tests for systemic toxicity* together with chemical characterization support the substantial equivalent of the subject device.
- Gamma Sterilization Validation:** Gamma Sterilization validation was conducted to all Ditron sterile provided items with accordance to ISO 11137-2 and AAMI TIR33 (replaced by ISO 13004:2022 with no changes affecting the original sterilization validation) using the VDmax method. All aspects of the Gamma sterilization validation process and tests remained unchanged as cleared under K140728. The sterilization validation results supported the SAL of at least 10⁻⁶.

- **Pyrogen Testing (Bacterial Endotoxin):** Pyrogen testing is performed using LAL (Limulus Amebocyte Lysate) method. The TPI is part of the routine quarterly LAL testing to comply with the testing limit of 20EU per device. The test is performed in accordance with ANSI/AAMI ST72 standard, USP <161> and USP <85>.
- **Steam Sterilization Validation:** Steam Sterilization validation was conducted to all Ditron abutments that are provided non-sterile and intended to be sterilized by the user at the clinic. The sterilization validation was conducted in accordance to ISO 17665 parts 1 and 2 and; ANSI AAMI ST79 using the overkill / half-cycle method. All aspects of the Steam sterilization validation process and tests remained unchanged as cleared under K140728. The steam sterilization validation results supported the SAL of at least 10^{-6} .
- **Surface testing:** The implants' surface was evaluated by SEM scans and EDS analyses. All surface tests results met Ditron's specifications.
- **Fatigue Testing:** There has been no change in the final configuration of the Ditron Dental Implants and Abutments system configuration.
Being similar in dimensions to the primary predicate, the TPI provided in straight configuration only and in one-piece design, does not alter the worst-case scenario.
The fatigue tests cleared under K140728 were conducted using worst case configuration and with accordance to ISO 14801 and FDA Guidance document for *Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*. Since the previously conducted tests cover the additional TPI Implant and abutments, these tests were not repeated.
- **Implant-Bone Contact Analysis** (applicable for short implants with a length of 6.0mm): There has been no change in the surface contact, and therefore, these tests were not repeated.
- **Implant Surface Area Analysis** (applicable for short implants in length of 6.0mm): There has been no change in the surface area and therefore these tests were not repeated.
- **Comparative pull-out test** (applicable for short implants in length of 6.0mm): The previously cleared MPI model was tested using a worst-case configuration and therefore no additional testing was conducted.
- **Shelf life:** Shelf life and package integrity along 5 years was validated previously within Ditron K140728 cleared products. This test was not repeated since all aspects of packaging and sterile barrier materials, process and process parameters are identical for all Ditron implants (subject devices and cleared devices) as cleared under K140728. ISO 11607-1 standard was followed in order to establish 5 years shelf life and package integrity. All tests met their acceptance criteria.
- **MRI Compatibility:** MRI Compatibility was established based on evaluation against scientific literature (Woods et al., "*Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices*") and product properties. It was concluded that the device is eligible to bear MR Conditional labeling.

Following the above-described tests and evaluations, it was concluded that the tested devices, whether conducted on the TPI itself or leveraged from Ditron's own discussed predicate devices, passed all tests and successfully met all acceptance criteria and tests' requirements.

8. Substantial Equivalence Conclusion:

The subject TPI dental implants and abutments have the same indications for use, technological characteristics, mode of operation and performance specifications as the above identified predicate and reference devices. A predicate device for each difference was presented, Similarities and differences were addressed and discussed, and no safety or effectiveness questions were raised.

Based upon the comparison and information described above, Ditron Dental has concluded that its additional TPI dental implants and abutments are substantially equivalent to the discussed primary predicate and reference devices.