Ditron Dental LTD
% Shifra Hoch
RA Consultant
Talmed Ltd.
M.P. Upper Galilee
Ramot Naftali, 1383000
ISRAEL

December 16, 2024

Re: K243066
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: September 25, 2024
Received: September 30, 2024

Dear Shifra Hoch:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K243066

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 chewing function of patients with fully or partially edentulous:

- Two stages: MPI, ULT, API, CPI, MPC, APC, CPC and UPC models
- One stage: OPI and TPI models

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

The Two stages and One stage implants are indicated for temporary or long-term use. They 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, TPI, MPC, APC, CPC and UPC models are indicated for immediate loading (except for MPI, and API 6mm length) in single- and multi-tooth restoration, when good primary stability is achieved and 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.

The Temporary Titanium and PEEK Abutments are indicated to be used on Ditron implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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Ditron Dental Ltd.
2 Haofe St. 7878002 Ashkelon, Israel
www.ditrondental.com

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

**Date Prepared:** December 10, 2024

## 1. Submitter

**Company Name:** Ditron Precision Ltd.
**Address:** 2 Haofe St Ashkelon, 78150 Israel
**Phone and E-mail:** +972-8-6711841; ariel@ditronprecision.com

**Contact Person:**
**Name:** Ms. Shifra Hoch – RA Consultant
**Address:** Talmed Ltd. Ramot Naftali, M.P Upper Galilee, 1383000, Israel
**E-mail:** shifra.hoch@talmed.co.il

## 2. Device:

**Common or usual name:** Dental Implants and Abutments
**Proprietary/Trade name:** Dental Implants and Abutments
**Implants subtypes:**
- MPC (Conical Connection Molecular Precision Implant)
- APC (Conical Connection Advanced Precision Implant)
- UPC (Conical Connection Ultimate Precision Implant)
- CPC (Conical Connection Cylindrical 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 Dental - Dental Implants and Abutments, cleared under K140728.
- **Reference Device:** Ditron Dental - Dental Implants and Abutments, cleared under K161497.
- **Reference Device:** Ditron Dental - Dental Implants and Abutments, cleared under K233231.
- **Reference Device:** Neodent Implant System - GM Line, cleared under K163194.
- **Reference Device:** Neodent Implant System - Temporary Abutments, cleared under K191191.
- **Reference Device:** Zest Anchors, Inc. LOCATOR® Implant Anchor Abutment, cleared under K072878.
- **Reference Device:** Straumann USA, LLC. Straumann Healing Caps, cleared under K130808.

## 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 types:**
  - **MPC (Conical Connection Molecular Precision Implant)**
  - **APC (Conical Connection Advanced Precision Implant)**
  - **UPC (Conical Connection Ultimate Precision Implant)**
  - **CPC (Conical Connection Cylindrical Precision Implant)**

The Conical Connection (CC) implants include a conical connection platform (Morse taper). The intended use, materials, drilling protocol, thread designs and bone interface of the subject Conical Connection implants (MPC, UPC, APC and CPC) are identical to Ditron's cleared Internal Hex connection platform implants (MPI, ULT, API and CPI, respectively). The CC implants include color anodization for aesthetic purposes. The CC compatible Cover and Prosthetic Screws are color anodized as well.

The MPC/APC/CPC/UPC Implants are available in diameters of 3.5mm, 3.75mm, 4.2mm, 5.0mm, and 6.0mm, with lengths of 8.0mm, 10mm, 11.5mm, 12mm, 13mm, 14mm, and 16mm. Additionally, a 6.5mm length is offered for MPC/APC/CPC implants in 4.2mm, 5.0mm, and 6.0mm diameters, and a 7.0mm length is available for UPC implants in 4.2mm, 5.0mm, and 6.0mm diameters.

- **An additional Abutment type: CC Healing Caps and SRA Healing Caps Abutments –** The CC Healing Caps are color-anodized for aesthetic purposes. They are used for the maintenance of the soft tissue during the osseointegration phase of Ditron CC implants to be rehabilitated using the late loading technique. They are available in diameters of 3.5, 4.5 and 5.5mm and the following gingival heights: 0.8, 1.5, 2.5, 3.5 and 4.5mm.
- **An additional Abutment type: CC Cement Retained Abutments –** the CC Anatomic/Universal straight/angulated abutments are Cement-Retained Abutments. They are intermediary prosthetic components to be installed onto Ditron's CC implants to support the final prosthesis. They are available as straight (0°) or angulated (15° and 25°) in diameters: 3.5, 4.5 and 5.5mm and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5 mm.
- **An additional Abutment type: CC Single-Unit and Multi-Unit Abutments -** The CC Screw-retained Single Unit Abutment and Multi Unit Abutments are intermediary prosthetic components to be installed onto CC Ditron's implants to support the final prosthesis. They are available as straight (0°) or angulated (17° and 30°) and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.0 mm. The Single Unit abutment height is up to 4.5mm only.
- **An additional Abutment type: CC Temporary Titanium Abutments -** The CC Temporary Titanium Abutments are temporary intermediary prosthetic components to be installed onto the Ditron's CC implants to support the provisional prosthesis for up to 6 months. They are available as straight (0°) in diameters: 3.5 and 4.5mm and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5mm.
- **An additional Abutment type: CC Temporary PEEK Abutments -** The CC Temporary PEEK Abutments are temporary intermediary prosthetic components to be installed onto Ditron's CC implants to support the provisional prosthesis for up to 6 months. They are composed of a customizable cylindrical body made of PEEK and a non-customizable base made of titanium. They are available in diameters of 4.5 and 6.0mm and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5mm.
- **An additional Abutment type: CC Liberator Overdenture Abutment -** The CC Liberator Overdenture Abutment is similar in design to Ditron's cleared Liberator abutment, except for the addition of Titanium Nitride (TiN) coating on the subject device. It is available in the following gingival heights: 0.5, 1.0, 2.0, 3.0, 4.0, 5.0 and 6.0mm.
- **An additional Abutment type: SRA Titanium Coping Abutments –** The SRA Titanium Coping Abutment is suitable for use with the CC Screw-retained single Abutments. It connects to the abutment using one of the designated abutment screws. They are available in short (L4.85mm) and long (L11mm) versions.
- **Modification to Cleared Titanium Abutments** – Addition of Laser Marking for identification as an option for all of the Ditron Dental cleared Titanium Abutments (K140728, K161497, K233231).
- **Modification to Cleared Liberator and TPI Overdenture Abutments –** Addition of TiN coating to Ditron's cleared Liberator abutment (K161497) and the cleared TPI Liberator Overdenture Abutment (K233231).

## 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 chewing function of patients with fully or partially edentulous:

- Two stages: MPI, ULT, API, CPI, MPC, APC, CPC and UPC models
- One stage: OPI and TPI models

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

The Two stages and One stage implants are indicated for temporary or long-term use. They 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, TPI, MPC, APC, CPC and UPC models are indicated for immediate loading (except for MPI, and API 6mm length) in single- and multi-tooth restoration, when good primary stability is achieved and 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.

The Temporary Titanium and PEEK Abutments are indicated to be used on Ditron implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.

## 6. Technological Characteristics and Substantial Equivalence:

The subjected devices are substantially equivalent to Ditron's Dental Implants and Abutments that were cleared under K140728, K161497 and K233231, and to Neodent Implant System - GM Line, cleared under K163194, Neodent Implant System - Temporary Abutments, cleared under K191191, Zest Anchors, Inc. LOCATOR® Implant Anchor Abutment, cleared under K072878, and Straumann USA, LLC. Straumann Healing Caps, cleared under K130808, as identified above under the 'predicate devices' section.

A tubular substantial equivalence is presented below:

**Table 1: Indications for Use Comparison Table**

| Device Name | | Indications for Use |
|---|---|---|
| **Subject Device** | **Ditron's Dental Implants and Abutments** | 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 chewing function of patients with fully or partially edentulous:<br>• Two stages: MPI, ULT, API, CPI, MPC, APC, CPC and UPC models<br>• One stage: OPI and TPI models<br>The 3.3mm and 3.0mm diameter implants (OPI and TPI, MPI and API) are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.<br>The Two stages and One stage implants are indicated for temporary or long-term use. They 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.<br>MPI, ULT, API, CPI, OPI, TPI, MPC, APC, CPC and UPC models are indicated for immediate loading (except for MPI, and API 6mm length) in single- and multi-tooth restoration, when good primary stability is achieved and with appropriate occlusal loading.<br>The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration.<br>The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.<br>The Temporary Titanium and PEEK Abutments are indicated to be used on Ditron implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability. |
| **Primary Predicate Device** | **Ditron's Dental Implants and Abutments (K140728)** | 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.<br>• Two stage: MPI, and CPI models<br>• One stage: OPI model<br>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.<br>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.<br>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.<br>The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration.<br>The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration. |
| **Reference Device** | **Ditron's Dental Implants and Abutments (K161497)** | 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.<br>• Two stage: MPI, ULT, API and CPI models<br>• One stage: OPI model<br>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.<br>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.<br>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.<br>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.<br>The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration.<br>The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration. |
| **Reference Device** | **Ditron's Dental Implants and Abutments [TPI Implant] (K233231)** | 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.<br>• Two stage: MPI, ULT, API and CPI models |

| | | |
|---|---|---|
| | | • One stage: OPI and TPI models<br>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.<br>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 longterm fixation of new or existing crown, bridge and prosthesis and protection of graft sites.<br>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 ocolusal loading.<br>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.<br>The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration.<br>The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration. |
| **Reference Device** | **Neodent Implant System - GM Line (K163194)** | The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.<br>Indications for Use for GM Titanium Base abutments:<br>Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations.<br>All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.<br>Indications for Use for GM Pro Peek Abutments:<br>The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability. |
| **Reference Device** | **Neodent Implant System - Temporary Abutments (K191191)** | The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Neodent Implant System - Temporary Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. |
| **Reference Device** | **Zest Anchors, Inc. LOCATOR® Implant Anchor Abutment (K072878)** | The Locator Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or<br>partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla. |
| **Reference Device** | **Straumann USA, LLC. Straumann Healing Caps (K130808)** | Closure screws, healing caps, and healing abutments are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Customizable healing abutments made of PEEK are for use for up to six months. |

**Indication for Use Substantial Equivalence Discussion:**

The Indications for use for the subject device and the primary predicate device K140728 and the reference devices K161497 and K233231 are identical. The reference device Neodent Implant System - GM Line (K163194) is indicated for similar indications as the subject device, and the Neodent Pro PEEK Abutments have identical indication for use to those of the subject device's CC Temporary Peek Abutments. This Neodent reference device includes digitally designed copings and crowns that is not part of the subject device and therefore their intended use in not applicable. The reference device Neodent Implants - Temporary Abutments (K191191) are indicated for similar indications as the subject devices CC Temporary Titanium Abutments and are also used for up to 6 months. The reference devices Zest's Locator (K072878) and Straumann Healing Caps (K130808) indications for use are included in the subject device's indications for use. To conclude, the indications for use of the subject device and the predicate and reference devices are substantially equivalence as they are either the same or are included in the subject devices' indication for use.

**Table 2: CC Implants - Technological Characteristics Comparison**

| Feature | Subject Device | Primary Predicate Device | REFERENCE DEVICES | | |
|---|---|---|---|---|---|
| | **Ditron's Dental Implants and Abutments [Conical Connection]** | **Ditron's Dental Implants and Abutments (K140728)** | **Ditron's Dental Implants and Abutments (K161497)** | **Ditron's Dental Implants and Abutments [TPI] (K233231)** | **Neodent Implant System - GM Line (K163194)** |
| **Implant Bone Contacting Surface Design** | MPI Surface design | MPI Surface design | MPI Surface design | MPI Surface design | N/A |
| | API Surface design | N/A | API Surface design | N/A | |
| | ULT Surface design | N/A | ULT Surface design | N/A | |
| | CPI Surface design | CPI Surface design | N/A | N/A | |
| **Raw Material** | Ti-6Al-4V-ELI | Ti-6Al-4V-ELI | Ti-6Al-4V-ELI | Ti-6Al-4V-ELI | Titanium Grade 4 |
| **Implant Construction** | Machined | Machined | Machined | Machined | Machined |
| **Implant Surface Treatment** | • Sand alumina large grit blasting and Acid etching<br>• Color anodization | Sand alumina large grit blasting and Acid etching | Sand alumina large grit blasting and Acid etching | • Sand alumina large grit blasting and Acid etching<br>• Color using anodization (Blue, Yellow-gold, Pink-Purple and Green) of the tissue level implant neck portion | N/A |
| **Implant to Abutment Connection** | Ditron Conical Connection interface; 16° Morse taper with optional anti-rotational features | Ditron Internal Hexagon connection interface | Ditron Internal Hexagon connection interface | N/A | GM interface; 16° Morse taper with optional anti-rotational features |
| **Implant Diameter and Length** | **MPC:** OD 3.5, 3.75 mm: L8-16 mm; OD 4.2-6.0 mm: L6.5-16 mm | **MPI:** OD 3.5-6.0 mm; L8-16 mm | **MPI:** OD 3.3-3.75 mm: L8-16 mm; OD 4.2-6.0 mm: L6-16 mm | N/A | OD 3.5-5.0 mm<br>L8 - 18 mm |
| | **APC:** OD 3.5, 3.75 mm: L8, -16 mm; OD 4.2-6.0 mm: L6.5-16 mm | N/A | **API:** OD 3.3-3.75mm: L8-16mm OD 4.2-6.0mm: L6-16. | | |
| | **UPC:** OD 3.75- 6.0 mm: L7-16 mm | N/A | **ULT:** Ø3.5-6.0 mm; L7-16 mm | | |
| | **CPC:** OD 3.5, 3.75 mm: L8, 10, 11.5, 12, 13, 14, 16 mm; OD 4.2. 5.0, 6.0 mm: L6.5, 8, 10, 11.5, 12, 13, 14, 16 mm | **CPI:** OD 3.75-6.0 mm; L8-16 mm | **CPI:** OD 3.75-6.0 mm; L8-16 mm | | |
| **Maximum Abutment Angle** | 30º | 30º | 30º | N/A | 30º |
| **Self-life** | 5 Years | 5 Years | 5 Years | 5 Years | 5 Years |
| **Sterilization Method** | Gamma Irradiation | Gamma Irradiation | Gamma Irradiation | Gamma Irradiation | Gamma Irradiation |

**Table 3: Abutments – General - Technological Characteristics Comparison**

***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 CC implant and its associated abutments, followed by each variation, identified and addressed by individually by its own, as follows.*

| Feature | Subject Device | Primary Predicate Device | Reference Devices | | | | |
|---|---|---|---|---|---|---|---|
| | **All Subject Abutments** | **Ditron's Dental Implants and Abutments (K140728)** | **Ditron's Dental Implants and Abutments (K161497)** | **Ditron's Dental Implants and Abutments [TPI] (K233231)** | **Neodent Implant System - GM Line (K163194)** | **Straumann USA, LLC. Straumann Healing Caps (K130808)** | **Neodent Implant System - Temporary Abutments (K191191)** |
| Indications for Use | As specified in Table 1 for each device (subject device, predicate device and reference devices), since the indications for use statement refers to both implants and abutments as an integral system. | | | | | | |
| Abutment Connection | Ditron Conical Connection interface; 16° Morse taper | Ditron Internal Hexagon connection interface | Ditron Internal Hexagon connection interface | N/A | GM interface; 16° Morse taper | N/A | GM interface; 16° Morse taper |
| Material | Titanium 6Al-4V-ELI with or without PEEK | Titanium 6Al-4V-ELI | | | Titanium 6Al-4V-ELI with or without PEEK | Titanium 6Al-4V-ELI | |
| Surface Treatment | **Titanium Abutments:** Color anodization and laser marking | None | None | **Titanium abutments:** Color Anodization | Healing Cap and Cover Screws are color anodized | Healing Abutments with laser marking on titanium with or without color anodization. | None |
| Sterilization Method | **Cover Screws:** Gamma Irradiation **Other abutments:** Provided non-sterile | **Cover Screws:** Gamma Irradiation **Other abutments:** Provided non-sterile | **Cover Screws:** Gamma Irradiation **Other abutments:** Provided non-sterile | **Cover Screws:** Gamma Irradiation **Other abutments:** Provided non-sterile | Provided sterile by Ethylene Oxide | Provided sterile by radiation | Provided sterile by Ethylene Oxide |
| End-User Sterilization | **Cover Screws:** Sterile Provided **Other abutments:** Moist steam sterilization | **Cover Screws:** Provided sterile **Other abutments:** Moist steam sterilization | **Cover Screws:** Provided sterile **Other abutments:** Moist steam sterilization | **Cover Screws:** Provided sterile **Other abutments:** Moist steam sterilization | Provided sterile | Provided sterile | Provided sterile |
| 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 | **Cover Screws:** Packaged with implant. **Other abutments:** Prosthetic Pouch | Prosthetic Pouch | Prosthetic Pouch | Prosthetic Pouch |
| Single use | Yes | Yes | Yes | Yes | Yes | Yes | Yes |

**Table 4: CC Healing Caps - Technological Characteristics Comparison**

| | Subject Device | Reference Device |
|---|---|---|
| **Feature** | **CC Healing Caps** | **Neodent's Healing Abutment (K163194)** |
| **Diameter** | Ø3.5- 5.5mm | Ø3.3- 6.5mm |
| **Gingiva Height** | 0.8-4.5mm | 0.8-5.5mm |
| **Angulation** | O° | O° |
| **Construction** | Machined with anodization | Machined with anodization |
| **Shape** | Concave | Concave |

**Table 5: SRA Healing Caps - Technological Characteristics Comparison**

| **Feature** | **Subject Device** | **Reference Device** |
|---|---|---|
| | **SRA Healing Caps** | **TPI Healing Cap (K233231)** |
| **Diameter** | 4.8mm | 4.8mm |
| **Height** | 3.5- 5.5mm | 3.5- 5.5mm |
| **Shape** | Cylindrical | Cylindrical |
| **Construction** | Machined with anodization | Machined with anodization |
| **Abutment Connection** | Straight SRA prosthetic platform | Straight TPI prosthetic platform |

**Table 6: CC Cement Retained Abutments - Technological Characteristics Comparison**

| **Feature** | **Subject Device** | **Primary Predicate Device** |
|---|---|---|
| | **CC Cement Retained Abutments** | **Ditron's Angulated Anatomic and Straight Abutments (K140728)** |
| **Diameter** | 3.5- 5.5 mm | 3.5- 5.6 mm |
| **Gingival Height** | 0.8-4.5 mm | 1.0- 7.0mm |
| **Angulation** | Straight (0°) or angulated (15° and 25°) | Straight (0°) or angulated (15° and 25°) |
| **Connection** | Engaging | Engaging |
| **Shape** | Rotational | Rotational |
| **Retention type** | Cement | Cement |

**Table 7: CC Single-Unit and Multi-Unit Abutments - Technological Characteristics Comparison**

| Feature | Subject Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | **CC Single-Unit (SU) and Multi-Unit (MU) Abutments** | **Ditron's Bar Retained (Straight) and Multi-Unit (angulated) Abutments (K140728)** | **Ditron's Straight and angulated Multi-Unit Bar Retained Abutments (K161497)** |
| **Diameter** | 4.8mm | 4.8mm | 4.8mm |
| **Length** | 1.5-5.0 mm | 1.0-4.0mm | 4.0- 6.0mm |
| **Angulation** | Straight (0°) or angulated (17° and 30°) | Straight (0°) or angulated (17° and 30°) | Straight (0°) or angulated (17° and 30°) |
| **Construction** | Machined with anodization | Machined | Machined with anodization |
| **Connection** | Straight: Non-engaging<br>Angulated: Engaging | Straight: Non-engaging<br>Angulated: Engaging | Straight: Non-engaging<br>Angulated: Engaging |
| **Retention type** | Screw retained | Screw retained | Screw retained |

**Table 8: CC Temporary Titanium Abutments (CC TTI) - Technological Characteristics Comparison**

| Feature | Subject Device | Reference Device |
|---|---|---|
| | **Temporary Titanium Abutments** | **Neodent Implant System - Temporary Abutments (K191191)** |
| **Connection** | Bridges: Non-Engaging; Crowns: Engaging | Bridges: Non-Engaging; Crowns: Engaging |
| **Diameter** | 3.5-4.5mm | 3.5-4.5mm |
| **Retentive Portion Height** | 12mm | 10mm |
| **Shape** | Cylindrical with retention grooves | Cylindrical with retention grooves |
| **Angulation** | 0° | 0° |
| **Duration** | 180 days | 180 days |

**Table 9: CC Temporary PEEK Abutments (CC TTP) - Technological Characteristics Comparison**

| Feature | Subject Device | Reference Device |
|---|---|---|
| | **Temporary PEEK Abutments** | **Neodent GM Pro Peek Abutment (K163194)** |
| **Connection** | Engaging | Engaging |
| **Material** | Titanium 6Al-4V-ELI and PEEK | Titanium 6Al-4V-ELI and PEEK |
| **Diameter** | 4.5 - 6.0mm | 4.5 - 6.0mm |
| **Gingival Heights** | 0.8 - 5.5 mm. | 0.8 - 5.5 mm |
| **Height** | Initial interocclusal height 9.5mm and can be customized up to 5.0 mm | Initial interocclusal height 9.2mm and can be customized up to 5.0 mm |

| Feature | Subject Device | Reference Device |
|---|---|---|
| | **Temporary PEEK Abutments** | **Neodent GM Pro Peek Abutment (K163194)** |
| **Angulation** | 0° | 0° |
| **Duration** | 180 days | 180 days |

**Table 10: CC Liberator Overdenture - Technological Characteristics Comparison**

| Feature | Subject Device | Reference Device | |
|---|---|---|---|
| | **CC Liberator Overdenture** | **Ditron's Liberator (K161497)** | **Zest LOCATOR Implant Anchor Abutment (K072878)** |
| **Diameter of connection with overdentures** | 3.86mm | 3.86mm | N/A |
| **Height** | 0.5 - 6.0mm | 2.35 - 6.35mm | |
| **Shape** | Cylindrical abutments for overdentures attachment system | Cylindrical abutments for overdentures attachment system | |
| **Abutment Coating** | TiN Coating | None | TiN Coating |

**Table 11: SRA Titanium Coping Abutments- Technological Characteristics Comparison**

| Feature | Subject Device | Reference Device |
|---|---|---|
| | **SRA Titanium Coping Abutments** | **TPI Titanium Copings Abutment [Crown] K233231)** |
| Connection | Engaging | Engaging |
| Diameter | 4.8mm | 4.8mm |
| Height | Short Version L4.85mm<br>Long Version L11.0mm | Short Version L4.85mm<br>Long Version L11.0mm |
| Shape | Cylindrical with retention grooves | Cylindrical with retention grooves |
| Abutment Connection | Straight SRA prosthetic platform:<br>external hexalobular | Straight TPI prosthetic platform:<br>external hexalobular |

## 7. Non-clinical Performance Data:

The following non-clinical tests were performed in order to demonstrate the substantial equivalence of the additional CC 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 that the subject device is substantial equivalent to the predicate 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 $10^{-6}$.
- **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:** There has been no change in the surface of the implants, and therefore, these tests were not repeated.
- **Fatigue Testing**: Fatigue tests 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* and demonstrated that the subject device is substantial equivalent to the predicate device.
- **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.
- **TiN Coating evaluation:** TiN coating was assessed using static and dynamic shear tests (ASTM F1160-14), static tension tests (ASTM F1147-05), and abrasion resistance tests (ASTM F1978-22). All tests met acceptance criteria, confirming substantial equivalence to the reference devices.
- **MRI Compatibility:** MRI Compatibility was established based on evaluation against scientific literature and product properties. It was concluded that the device is eligible to bear MR Conditional labeling.

The non-clinical performance testing conducted supports the substantial equivalence of the additional CC Dental Implants and Abutments to the predicate devices. Biocompatibility testing in accordance with ISO 10993 standards confirmed the materials are biocompatible. Gamma and steam sterilization validations demonstrated compliance with applicable standards, ensuring sterility assurance levels (SAL) of at least $10^{-6}$. Fatigue testing, performed under worst-case conditions per ISO 14801, confirmed mechanical strength equivalent to the predicate. No changes were made to the implant surfaces, surface area, or shelf-life

characteristics validated under K140728, and additional testing was not required. TiN coating evaluation, including shear, tension, and abrasion resistance testing per ASTM standards, met all acceptance criteria. MRI compatibility was established through evaluation of product properties and scientific literature, supporting MR Conditional labeling. Collectively, these results establish that the subject device is as safe and effective as the predicate devices.

## 8. Substantial Equivalence Conclusion:

The subject CC 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 CC dental implants and abutments are substantially equivalent to the discussed primary predicate and reference devices.