DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 28, 2016

Ditron Precision Ltd.
% Tali Hazan
Regulatory Consultant
Talmed Ltd.
Ramot Naftali, M.P Upper Galillee
Ramot Naftali, 13830000
ISRAEL

Re: K161497
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, 2016
Received: October 3, 2016

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 (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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161497

Device Name
Dental Implants and Abutments
Implants' subtypes: MPI – Molecular Precision Implant, ULT - Ultimate, API - Advanced Precision Implant, CPI – Cylindrical Precision Implant, OPI – One Piece Implant.

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 model

The 3.3 and 3.0 mm 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.

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.
MPI, ULT, API, CPI and OPI designs are indicated for immediate loading (except for MPI and API in 6mm 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 6mm 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

1. Date Prepared: October 22, 2016

2. 510(k) owner name:

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3. Device Name and Classification:

Common or usual name: Dental Implants and Abutments
Proprietary/Trade name: Dental Implants and Abutments
Implants' subtypes: MPI – Molecular Precision Implant;
ULT – Ultimate Precision Implant; **API** – Advanced Precision Implant;
CPI – Cylindrical Precision Implant; **OPI** – One Piece Implant.

Classification name Ditron *Dental Implants and Abutments* have been classified as ***Class II*** devices under the following classification names:

Classification Name	21 CFR Ref.	Product Code	Panel
Endosseous Dental Implant	872.3640	Primary: DZE	DAGRID, Dental
		Secondary: NHA	

4. Predicate Device:

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

- Ditron Precision Ltd's legally marketed Dental Implants and Abutments, cleared under 510(k) number K140728 (primary predicate device), *and;*
- MIS Implants Technologies Ltd's MIS Short Implants (SEVEN), cleared under 510(k) number K103089 (reference predicate device).
- Implant Direct LLC's Legacy3 6mm Length implants, cleared under 510(k) number K131097 (reference predicate device).

5. Device description:

This submission covers the changes related to Ditron's dental implants and abutments. The addition of more products' variations is to offer dental surgeons additional implant options for patient treatment.

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

- **Modification to the MPI Model –**
  The MPI features an expanding tapered implant body with double-thread self-tapping design to gradually condense the bone.
  The MPI model remained the same as cleared under K140727 except for the following modifications:
  Length: 6mm (only with diameter of 4.2mm, 5.0mm and 6.0mm),
  Diameters: 3.3 (with lengths 8.0mm, 10mm, 11.5mm, 13mm and 16mm).
  The 'groove' between thread leads which is part of the MPI design in all dimension variations, was removed only at the OD 3.3mm design.
  All MPI dimensions are detailed in section 7 of this 510(k) summary.

- **An additional implant type: ULT (Ultimate)** –
  The ULT design is based on Ditron's cleared MPI model. The ULT features an expanding tapered implant body and a truncated-cone profile provides root-form morphology of the tooth root.
  The implant has a self-tapping design and micro threads at the top of the implant.
  All ULT implant dimensions are detailed in section 7 of this 510(k) summary.

- **An additional implant type: API (Advanced Precision Implants)** –
  The API design is based on Ditron's cleared MPI model. The API features an expanding tapered implant body with double-thread self-tapping implant body and apex design. The design is intended for subcrestal placement.
  The implant beveled collar shifts the implant-abutment junction inward, in order to achieve platform-switching configuration. Only the 6mm API model includes a 'groove' while the others do not. All API implant dimensions are detailed in section 7 of this 510(k) summary.

- **An additional Abutment type: Milled Abutment** –
  The Milled Abutment design is based on Ditron's cleared Straight Abutments. The Milled Abutment allows the dentist to produce customized abutments (no additional angular correction).
  No CAD/CAM design and fabrication is allowed for the Milled Abutment models. Only hand-milling or casting may be used for abutment modification.

- **An additional Abutment type: Liberator Abutment** –
  The Liberator Abutment is an overdenture retention abutment. Its design is based on Ditron's cleared Ball Attachment abutments. The Liberator abutments are used for tissue and implant support of overdentures. Typically with two or more relatively parallel implants. Liberator overdenture retention abutments provide firm retention and stabilization to the overdenture.
  The Liberator Abutment is available is several length dimensions of 0.5, 1.0, 2.0, 3.0, 4.0 and 5.0mm.

- **Straight Multi-Unit Abutment –**
  Additional two lengths were added to Ditron's cleared Straight Multi-Unit abutments. These length dimensions are: 4.0mm and 5.0mm. All dimensions' variations of the straight Multi-Unit abutments are detailed in section 7 of this 510(k) summary.

All above described implants and abutments are made of biocompatible 6A1-4V-ELI Titanium grade.

6. Intended 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 model

The 3.3 and 3.0 mm 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.

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.
MPI, ULT, API, CPI and OPI designs are indicated for immediate loading (except for MPI and API in 6mm 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 6mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading.

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

7. Technological characteristics and Substantial Equivalence:

The subjected devices are substantially equivalent with Ditron's original Dental Implants and Abutments that were cleared under K140728 and MIS short implants, that were cleared under K103089, as identified above under 'predicate devices' section.
A certain difference in the MPI collar design versus MIS 'SEVEN' short implant was covered under Implant Direct Legacy3 implant that was cleared under 510(k) number K131097.

Two differences exist between the subject device and the primary predicate device indications for use statement. These differences are only related to the additional two-stage implant models (Ultimate and API) and to the 6mm length implants (MPI and API)

being excluded from the immediate loading claims. Other than these differences the indications for use are identical. The differences are not affecting the intended use since the new subject devices are meant to be used the same way as the primary predicate device. The exclusion of the immediate loading for the 6mm length implants only narrows the primary predicate device intended use, thus do not raise additional concerns.

Both modified and predicate devices have the same indications for use, same shape, design and characteristics. All changes differ the new device from the predicate devices were addressed and evaluated.

The **implants** substantial equivalence table is following presented:

Feature	Ditron Dental Implants and Abutments Predicate Device cleared under K140728	MIS SEVEN Implants Predicate Device cleared under K103089	Subject Ditron Dental Implants and Abutments - Subject Device -
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, and CPI models • One stage: OPI model 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	MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. MIS short implants are to be used only with straight 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 patient's chewing function. • Two stage: MPI, ULT, API and CPI models • One stage: OPI model The 3.3 and 3.0 mm 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. 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

Feature	Ditron Dental Implants and Abutments Predicate Device cleared under K140728	MIS SEVEN Implants Predicate Device cleared under K103089	Subject Ditron Dental Implants and Abutments - Subject Device -
	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, 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 shall be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments shall be used within 32 degrees of parallelism for a splinted restoration.		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 and OPI designs are indicated for immediate loading (except for MPI and API in 6mm 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 6mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading. The 30-degree multi-unit abutments shall be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments shall be used within 32 degrees of parallelism for a splinted restoration.
Material	Titanium 6Al-4V-ELI	Titanium 6Al-4V-ELI	Titanium 6Al-4V-ELI
Patient Population	Edentulous or partially edentulous individuals	Same population	Edentulous or partially edentulous individuals
Implant Models	MPI	MIS Short Implants (SEVEN)	MPI, ULT, API
Dimensions of two stage implants	OD= 3.5mm, 3.75 mm, 4.2 mm, 5.0 mm *for* L= 8.0 mm, 10 mm, 11.5 mm, 13 mm and 16 mm. OD= 6.0 mm *for* L=8.0 mm, 10 mm, 11.5 mm and 13 mm.	OD = 4.2, 5.0, 6.0 mm L = 6 mm	<u>MPI</u> OD=3.3 *for* L=8.0, 10.0, 11.5. 13 and 16 mm. OD=4.2, 5.0. 6.0 *for* L=6mm. <u>ULT</u> OD=3.5, 3.75, 4.2, 5.0, 6.0 mm *for* L = 7.0, 8.0 10.0,

Feature	Ditron Dental Implants and Abutments Predicate Device cleared under K140728	MIS SEVEN Implants Predicate Device cleared under K103089	Subject Ditron Dental Implants and Abutments - Subject Device -
			11.5 13, 16mm API OD=3.3, 3.5 3.75, 4.2, 5.0, 6.0mm *for* L=8, 10, 11.5,13.16 OD=4.2, 5.0 mm *for* L=6, 8, 10, 11.5,13, 16. OD=6.0 mm *for* L=6, 8, 10, 11.5, 13, 16.
Surface	Sand blasting & acid etching	Sand blasting & acid etching	Sand blasting & acid etching
Design	Conical screw	Conical screw	Conical screw
Sterilization	Sterile: Gamma	Sterile	Sterile: Gamma
Placement method	Placing the implant immediately after drilling	Same	Placing the implant immediately after drilling
Self-tapping	Yes	Yes	Yes
Connection type	Internal hex	Internal Hex	Internal hex
Maximum Abutment Angle	30^{o}	Straight only	30^{o} for all implants except for: Implants with L=6mm: straight abutment only, and; Implants with OD of less than 3.75mm: Up-to 25^{o} abutments only.

The **Abutments** substantial equivalence table is following presented:

Subject Abutments compared with Abutments Cleared under K140728				
Ditron P/N	**Ditron Abutment Name (*Made of Ti 6Al-4V-ELI)**	**Ditron Abutment Family Description**	**Ditron Model Name**	**Ditron Predicate Device Model *Made of Ti 6Al-4V-ELI**
ABT-MILL	Anatomic straight abutment with shoulder	Anatomic straight abutment with shoulder 6 mm. length	Anatomic straight abutment with shoulder	ABT-6050-2 Straight Abutment
MUA-10ST	Straight multi-unit Bar retained abutment	Straight multi-unit Bar retained abutment 1.0 mm. length	Straight multi-unit Bar retained abutment	BAR-9005 Straight multi-unit Bar retained abutment
MUA-20ST	Straight multi-unit Bar retained abutment	Straight multi-unit Bar retained abutment 2.0 mm length	Straight multi-unit Bar retained abutment	BAR-9015 Straight multi-unit Bar retained abutment
MUA-30ST	Straight multi-unit Bar retained abutment	Straight multi-unit Bar retained abutment 3.0 mm length	Straight multi-unit Bar retained abutment	BAR-9025 Straight multi-unit Bar retained abutment
MUA-40ST	Straight multi-unit Bar retained abutment	Straight multi-unit Bar retained abutment 4.0 mm length	Straight multi-unit Bar retained abutment	BAR-9025 Straight multi-unit Bar retained abutment
MUA-50ST	Straight multi-unit Bar retained abutment	Straight multi-unit Bar retained abutment 5.0 mm length	Straight multi-unit Bar retained abutment	BAR-9025 Straight multi-unit Bar retained

Subject Abutments compared with Abutments Cleared under K140728				
Ditron P/N	**Ditron Abutment Name (*Made of Ti 6Al-4V-ELI)**	**Ditron Abutment Family Description**	**Ditron Model Name**	**Ditron Predicate Device Model *Made of Ti 6Al-4V-ELI**
				abutment
LIB-ABT05	Liberator overdenture retention abutment	Liberator overdenture retention abutment 0.5 mm length	Liberator overdenture retention abutment	BAL-10005 Ball attachment abutment
LIB-ABT10	Liberator overdenture retention abutment	Liberator overdenture retention abutment 1.0 mm length	Liberator overdenture retention abutment	BAL-10005 Ball attachment abutment
LIB-ABT20	Liberator overdenture retention abutment	Liberator overdenture retention abutment 2.0 mm length	Liberator overdenture retention abutment	BAL-10020 Ball attachment abutment
LIB-ABT30	Liberator overdenture retention abutment	Liberator overdenture retention abutment 3.0 mm length	Liberator overdenture retention abutment	BAL-10030 Ball attachment abutment
LIB-ABT40	Liberator overdenture retention abutment	Liberator overdenture retention abutment 4.0 mm length	Liberator overdenture retention abutment	BAL-10040 Ball attachment abutment
LIB-ABT50	Liberator overdenture retention abutment	Liberator overdenture retention abutment 5.0 mm length	Liberator overdenture retention abutment	BAL-10050 Ball attachment abutment

Subject Abutments compared with Abutments Cleared under K140728				
Ditron P/N	**Ditron Abutment Name (*Made of Ti 6Al-4V-ELI)**	**Ditron Abutment Family Description**	**Ditron Model Name**	**Ditron Predicate Device Model *Made of Ti 6Al-4V-ELI**
LIB-ABT60	Liberator overdenture retention abutment	Liberator overdenture retention abutment 6.0 mm length	Liberator overdenture retention abutment	BAL-10060 Ball attachment abutment

8. Non-clinical performance data:

The following non-clinical tests were performed in order to assure the safety and effectiveness of the modified devices:

- **Biocompatibility –** Biocompatibility was established within Ditron 510(k) K140728 using the device chemical and biological tests. No changes took place in terms of the body contact 6A1-4V-ELI Titanium grade.
  The Cytotoxicity test was supported with chemical characterization tests utilizing exaggerated extractions conditions using three extracts and leachables/extractables analyses using acceptable methods (GC-MS, XPS).
  All tests were completed with satisfactory results. The tests were conducted with accordance to ISO 10993-1 and FDA Guidance for biological evaluation.
- **Gamma Sterilization Validation –** Gamma Sterilization validation was conducted to all Ditron sterile provided items with accordance to ISO 11137-2 and AAMI TIR33 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 with 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 tested within previous cleared 510(k) by SEM/EDS and XPS tests. All surface tests results met Ditron's specifications. Since there was no change in the surface treatment process, these tests were not repeated.
- **Fatigue Testing –** The modified subject products' were tested for Fatigue as follows:
  a) MPI Fatigue test report (OD 3.3mm implant with 25^{o} abutment) covering the API as well.
  b) ULT Fatigue test report (OD 3.5mm implant with 25^{o} abutment).
  The previously cleared MPI model was tested for fatigue using worst case configuration of OD3.5mm and 30^{o} multi-unit abutment within Ditron's cleared K140728 covering the cleared CPI model as well.
  The fatigue tests were conducted using worst case configuration considering the highest angulation as well as smallest diameter and wall thickness.
  The tests were conducted with accordance to ISO 14801 and FDA Guidance document for *Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*. The results met the test's requirements.
- **Implant-Bone Contact Analysis –** Contact surface area was analyzed in comparison to legally marketed device.
- **Implant Surface Area Analysis -** Implant actual surface area before surface treatment was compared to the predicate device.

- **Comparative pull-out test** of Ditron smallest implant with legally marketed device.
- **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.

Following the above described tests it was concluded that the tested devices passed all tests and successfully met all acceptance criteria and tests' requirements.

9. Conclusions:

The evaluation of Ditron's modified Dental Implants and Abutments non-clinical tests' results demonstrate that the devices are in-line with their specifications, labeling claims and they have been performed as intended.
It was concluded that the modified devices are as good as the predicate devices and that all performance tests' acceptance criteria were met.
Wherever certain differences exist, these differences were addressed and discussed.
Therefore, we believe that the new devices are substantially equivalent to their predicate devices previously cleared.