DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2014

Ditron Precision, Limited
C/O Ms. Tali Hazan
Regulatory Consultant
Ramot-Naftali
M.P Upper Galilee, 13830
ISRAEL

Re: K140728
Trade/Device Name: Dental Implants and Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 21, 2014
Received: September 25, 2014

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140728

Device Name: Dental Implants and Abutments

**Models names identification:*

- *MPI – Molecular Precision Implant*
- *CPI – Cylindrical Precision Implant*
- *OPI – One Piece Implant*

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, 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 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 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.

Prescription Use __✓___ (Part 21 CFR 801 Subpart D)

4-1

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ditron Precision Ltd, P.O.B. 5010, Ashkelon 78150, Israel
2 Haofe St. Southern Ind. Zone, Ashkelon 78780, Israel
Tel: +972-8-6711841 | Fax: +972-8-6711843

דיטרון תעשיות בע"מ, ת.ד. 5010, אשקלון 78150
רח' האופה 2, אזור התעשיה הדרומי, אשקלון
טל. 08-6711841 | פקס. 08-6711843

www.ditronprecision.com
www.ditrondental.com

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

1. Date Prepared: 15 March 2014

2. 510(k) Owner Name:

Ditron Precision Ltd.
Haofe 2St. Ashkelon, 78150, Israel
Phone: +972-8-6711841, Fax: +972-9-6711843, Email: orlev@ditronprecision.com

Contact person:
Ms. Tali Hazan – RA Consultant
Phone: +972-(0)50-5292-304
Fax: +972-(0)722448981
Email: tali.hazan@talmed.co.il

3. Device Name and Classification:

Common/Usual Name: Dental Implants and Abutments
Proprietary/Trade name(s): **MPI** – Molecular Precision Implant);
CPI – Cylindrical Precision Implant), and;
OPI – One Piece Implant.
Classification: Ditron *Dental Implants and Abutments* have been classified as ***Class II*** devices under the following classification names:

Regulation Description	Product Code	21 CFR Ref.	Panel
Endosseous dental implant	**Primary:** DZE **Secondary:** NHA	872.3640	DAGRID, Dental

4. Predicate Devices:

Ditron's *Dental Implants and Abutments* are substantially equivalent to the following Predicate Devices:

4.1 Alpha-Bio Tec® Dental Implant System (by Alpha-Bio Tec Ltd) cleared under K063364; product code DZE (Implant, Endosseous, Root-Form).

4.2 AB Dental Abutments (by AB Dental Ltd) cleared under K112440; product code NHA Endosseous Dental Implant Abutment.

4.3 Prismatik Dentalcraft Multi-Unit Abutments with Angulations 17^{o} and 30^{o} for Tapered Implant System (by Prismatik Dentalcraft Inc) cleared under K121688; product code NHA Endosseous dental implant.

5. Intended Use/Indications for Use:

The Ditron Dental Implant 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, CPI
- One stage: OPI

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.
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.

6. Device Description:

The Ditron Dental Implants and Abutments consist of one and two stage endosseous form dental implants, internal hexagonal implants and external hexagonal abutments, one piece implants system, cover screws and healing caps; abutment systems and superstructures and surgical instruments.

The **Molecular Precision Implant (MPI)** features an expanding tapered implant body. It is available in lengths of 8.0 mm, 10 mm, 11.5 mm, 13 mm and 16 mm with diameters of 3.5mm, 3.75 mm, 4.2 mm, 5.0 mm and 6.0 mm, except for the 16 mm length which is not available with a diameter of 6.0 mm.

The **Cylindrical Precision Implant (CPI)** is a cylindrical implant. It is available in lengths of 8.0 mm, 10 mm, 11.5 mm, 13 mm and 16 mm with diameters of 3.75 mm, 4.2 mm, 5.0 mm and 6.0 mm, except for the 16 mm length which is not available with a diameter of 6.0 mm.

The **One Piece Implant (OPI)** is a one piece implant with an integral abutment designed for one stage procedure and cemented restorations. It is available in lengths of 8, 10, 11.5, 13 and 16 mm with diameters of 3.0 and 3.3 mm

Straight Abutments can be used with two platforms; normal and slim. The straight abutments are available at the following lengths of 11.5 and 8.5 mm with a diameter of 4.5 mm, length of 8.5 mm and 6 mm with a diameter of 3.8 mm, length of 2 and 4 mm with a diameter of 5.6 mm.

The Anatomic Angulated Abutment has an anatomic configuration with ascending and descending shoulders the height of the neck varies between 1, 2 and 3mm and is available in 2 different lengths; 1 and 3 mm. These abutments are available with angles of 15^{o} and 25^{o}.

Angulated Abutments are suitable for multi-unit implant restorations and are available with angles of 15^{o} and 25^{o} with lengths of 8.5 mm and 11.5 mm.

Ball Retained Abutments feature a titanium ball for overdenture restoration and are available in the following dimensions: 0.5, 2, 3, 4, 5 and 6 mm. Less than 4mm post-height are suitable only for multi-unit loaded restorations.

Temporary Abutments require no cement and are supplied at lengths of 1, 2, 3, 5 and 7 mm.

Bar Retained Abutments less than 4mm post-height are suitable only for multi-unit loaded restorations and are supplied in the following dimensions: 0.5, 1.5, 2.5 mm.

Multi-Unit Bar Retained Abutments provides support and retention for muti-unit screw-retained restorations and are available in two heights: 0.5mm and 1mm, and; two angles: 17^{o} and 30^{o} for each height for multi-unit loaded restorations.

Screw Retained Abutment is a supporting structure used to support lateral or horizontal pressure as an anchorage for single tooth or more (bridge). The package is supplied with the abutment and the matching screw. Less than 4mm post-height are suitable only for multi-unit loaded restorations or for single-unit loaded restorations if used in combination with plastic sleeve per Ditron labeling.
Cover screw is made of titanium and supplied sterile with the implant.

All implants and body contact abutments are made of biocompatible Titanium 6Al-4V-ELI.

7. Substantial Equivalence:

The proposed Ditron Dental Implants and Abutments have similar indications for use, technological characteristics, mode of operation and, performance specification as the above identified predicate devices. The proposed device utilizes same intended use as the predicates and is placed using the same methodology as all of the selected predicate devices. Both the proposed and predicate devices function in the same manner providing support for prosthetic devices in the upper or lower jaw.

8. Performance Testing:

A series of safety and performance tests and evaluations were performed to demonstrate that Ditron's Dental Implant System does not raise any new issues of safety and effectiveness. These evaluations include fatigue, surface analysis, biocompatibility, sterilization validation and shelf life validation in order to assure maintaining of SAL 10^{-6} along the shelf life.

All results are supporting Ditron's labeling claims in order to establish substantial equivalency.

9. Summary and Conclusion:

We believe that Ditron Dental Implants and Abutments, which are the subject of this 510(k) submission, are substantially equivalent to the predicate devices cited above. The device constitutes a safe, reliable and effective medical device, meeting all declared requirements of its intended use and the device does not introduce new risks and does not present any new adverse health effects or safety potential risks to patients when used as intended.