Advanced Dental Solutions Ltd.
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510(k) SUMMARY

510(k) Number K 130462

Applicants Name: Paltop Advanced Dental Solutions Ltd.
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Contact Person: Tal Hammer-Topaz
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AUG 27 2013

Date Prepared: February 18th, 2013

Trade Name: Paltop Narrow Implant

Classification Name: Implant, Endosseous, Root-form

Common usual name: Dental Implant

Medical Specialty: Dental

Product Code: DZE, NHA

Device Class: Class II

Regulation Number: 872.3640

Review Panel: Dental Device Panel

Predicate Devices:

Paltop Narrow Implant is relying on the combination of the following predicate devices:

- Paltop Dental Implant System (Paltop Advanced Dental Solutions Ltd.) cleared under K112795; product code DZE, NHA (Implant, Endosseous, Root-Form).
- UNO Narrow Implant (MIS - Implant Technologies Ltd.) cleared under K092555; product code DZE, NHA (Implant, Endosseous, Root-Form).
- Osseospeed™ Narrow (ASTRA Tech AB) cleared under K080396; product code DZE,NHA (Implant, Endosseous, Root-Form)

Intended Use / Indication for Use:

The Paltop Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Device Description:

Paltop Narrow Implants, as other implants available in the market, are essentially a substitute for a natural tooth. Paltop Narrow Implants, as other implants available in the market, are one and two stage endosseous screw type implant with internal hexagonal connection, intended for single use. As other implants available in the market, they are fabricated from titanium alloy, Titanium -6 Aluminum 4 Vanadium ELI alloy, according to ASTM F136-98, a biologically compatible material to vital tissue, and surface treated with sand blasting and acid etching.

The Paltop Narrow Implant is a suitable treatment option when the possibility of placing a standard implants is limited due to physical conditions, where the horizontal space is

limited by adjacent teeth and roots, or in situations with a narrow alveolar ridge. By using a narrow implant the need for bone augmentation or orthodontic tooth movement can be avoided.

The Paltop narrow implants are 3.25mm-wide and are available in lengths of 10mm, 11.5mm, 13mm and 16mm.

Substantial Equivalence:

The proposed Paltop Narrow Implants have similar indications for use, technological characteristics, mode of operation and performance specification as the predicates MIS Implants and Astra-Tech Implants. The proposed devices have the same intended use as the predicates and are placed using the same methodology as the predicate devices. Both the proposed and predicate devices function in the same manner providing support for prosthetic devices in the upper or lower jaw.

Technological Characteristics – comparative table – Narrow Implants

	PALTOP Narrow Implants	PALTOP Dental Implant System	MIS UNO Narrow Implant	Astra Tech OsseoSpeed Narrow
K#		Cleared under K#112795	Cleared under K#092555	Cleared under K#080396
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Manufacturer	Paltop Advanced Dental Solutions Ltd.	Paltop Advanced Dental Solutions Ltd.	MIS Implant Technologies Ltd.	Astra Tech AB
Intended Use/ Indications for Use	The Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and	The Paltop Dental Implant System is 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. The Paltop	The UNO Narrow implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and	The OsseoSpeed Narrow is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. The device may be equally well in single-stage or two-stage surgical procedure. It is indicated for

	PALTOP Narrow Implants	PALTOP Dental Implant System	MIS UNO Narrow Implant	Astra Tech OsseoSpeed Narrow
	roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	roots, jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Mandibular central and lateral incisors must be splinted if using two or more ϕ3.0mm implnats adjacent to one another. . The UNO Narrow Implant is indicated for immediate implantation in the extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achived and the occlusal load is appropriate.	immediate implantation in extraction sites or implantation in partially healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediattely loaded when good primary stability is achived and functional load is appropriate. The OsseoSpeed Narrow product line shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. The fluoride-modified surface, though having a fluoride ion level far below the needed for caries prevention in theeth, provides a favorable substrate for bone attachment and osseointegration. OsseoSpeed Narrow is especially indicated for use in soft bone applications where implants with other implant surface treatment may be less effective.Because initial stability may be difficult to obtain in Type IV bone, immediate loading of sungle tooth restorations may not be appropriate in such situations.
Components	Dental implants, cover screws healing caps; abutment systems and superstructures;	Dental implants, cover screws healing caps; abutment systems and superstructures; surgical instruments.	Dental implants, cover screws healing caps; abutment systems and superstructures;.	Dental implants, cover screws healing caps; abutment systems and superstructures;.
Clinical Data	Not applicable	Not applicable	Not applicable	Not applicable

	PALTOP Narrow Implants	PALTOP Dental Implant System	MIS UNO Narrow Implant	Astra Tech OsseoSpeed Narrow
Supplied Sterile	Yes	Yes	Yes	Yes
Re-Use	No	No	No	No
Material Composition	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy
Surface treatment	Sand Blasting and Acid Etching	Sand Blasting and Acid Etching	Sand Blasting and Acid Etching	Fluride-modified surface
Shape	Screw type	Screw type	Screw type	Screw type
Length	10mm, 11.5mm, 13mm, 16mm	8mm, 10mm, 11.5mm, 13mm, 16mm	10mm, 11.5mm, 13mm, 16mm	11mm, 13mm, 15mm
Diameters	3.25mm	3.75mm, 4.2mm, 5.0mm	3.0mm	3.0mm
Abutments	Straight and up to 20º	Straight and up to 25º	Straight and up to 20º	Straight and up to 20º
Material Composition of Abutments	Titanium alloy,	Titanium alloy, Plastic (PEEK)	Titanium alloy, Plastic	Titanium alloy
Surface Treatment of Abutments	None	None	None	None

The Paltop Narrow Implants have the following similarities to their predicate devices:

- Have the same intended use
- Use the same operating principle
- Incorporate the same basic design
- Incorporate the same materials
- Have similar packaging
- Sterilized using the same procedures

Non Clinical Tests:

Risk analysis process was conducted to assess the impact of the modification of the device. Bench testing, verification and validation activities previously conducted to the standard device were re-evaluated for their applicability to the modified device. Fatigue testing of the modified device showed that implants are safe and effective and meets existing acceptance criteria. Other performance testing and validations (corrosion resistance, surface analysis, biocompatibility evaluation, sterilization validation and shelf life validation) previously conducted to the standard device were shown to be applicable to the modified design, as their results may not be affected by the dimensional changes.

Bench testing and validations demonstrates that the narrow implants are substantially equivalent to predicate devices and do not raise new issues of safety or effectiveness.

Clinical Tests:

Not applicable

Summary:

The evaluation of Paltop Narrow Implants do not raise any additional concerns regarding safety and effectiveness of the device and therefore Paltop Advanced Dental Solutions Ltd. believes that Paltop Narrow Implants may be considered as substantially equivalent to their predicate devices.

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

August 27, 2013

Paltop Advanced Dental Solutions Limited
C/O Mr. Tal Hammer-Topaz
Quality, Regulatory & Clinical Manager
Hashita 5, PO Box 3568
Caesarea 30889
ISRAEL

Re: K130462
Trade/Device Name: Paltop Narrow Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 25, 2013
Received: July 31, 2013

Dear Mr. Hammer-Topaz:

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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Advanced Dental Solutions Ltd.
PALTOP
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Indications for Use

510(k) Number: **K130462**

Device Name:

PALTOP Narrow Implant

The Paltop Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use __V_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.08.27 16:47:17 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: _____k130462_____