



Food and Drug Administration
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January 28, 2016

DenTack Implants Ltd
c/o Ms. Tali Hazan
Regulatory Consultant
Talmed Ltd
M.P. Upper Galilee
Ramot Naftali, 13830
ISRAEL

Re: K152188

Trade/Device Name: QUAD Dental Implants and Prosthesis
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 14, 2015
Received: December 17, 2015

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 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,



Tina Kiang -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K152188

Device Name

QUAD Dental Implants and Prostheses

Indications for Use (Describe)

DenTack QUAD Dental Implants and Prostheses are intended for surgical placement in the maxilla and/or in the mandible to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous jaws utilizing delayed loading or immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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 DENTACK'S QUAD
DENTAL IMPLANTS AND PROSTHESES**

DATE PREPARED: January 20, 2016

1. 510(K) OWNER NAME

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2. DEVICE NAME AND CLASSIFICATION

Common/Usual Name: Dental Implants and Prostheses

Proprietary/Trade name: *QUAD Dental Implants and Prostheses*

Classification: DenTack's *QUAD* device has been classified as **Class II** device under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
Endosseous dental implant	Primary: DZE	21 CFR 872.3640	Dental
	Secondary: NHA		



3. PREDICATE DEVICES

DenTack's *QUAD* Dental Implants and Prostheses are substantially equivalent to the following Predicate Devices (primary and secondary):

- 3.1 **Primary Predicate Device:** Sargon's Immediate Load Implant Model D; cleared under 510(k) number K981141 on June 23, 1999.
- 3.2 **Reference Predicate Device:** Biomet's Biomet 3i Dental Abutments and Restorative Components; cleared under 510(k) K072642 on December 20, 2002.
- 3.3 **Reference Predicate Device:** Nobel Biocare, NobelActive Internal Connection Implant; cleared under 510(k) K071370 on August 3, 2007.
- 3.4 **Reference Predicate Device:** Implant Direct, Legacy3 6mm Length Implants; cleared under 510(k) K131097 on August 22, 2013.

4. DEVICE DESCRIPTION

DenTack has developed a range of expandable dental implants made of Titanium to serve the need of patients that require partial or complete tooth restoration.

The implant is placed so its apical end is in the trabecular (spongy) bone like any other implant. Once in place, the apical portion of the implant is expanded to achieve increased contact surface area with the surrounding bone.

The system also includes various accessories that attach to the implant.

All DenTack's implant bodies are made of a combination of Titanium alloy according to ASTM F136 and c.p. titanium according to ASTM F67. Abutments are made of same Titanium alloy while denture components are made of stainless-steel and polymers.

DenTack's *QUAD* Implants are available in outer diameter (OD) of: 3.75 and 4.1 mm. The implants' length dimensions are from 7 to 11 mm.



DenTack's Prostheses are identified as follows:

Metal housing	Direct screw platform
Plastic cup	Straight abutments
Straight Multi-unit Sleeve	Screw retained abutments
Straight Multi-unit Screw	Straight Multi-unit abutments
Angled abutments 15° and 25°	Healing caps
Angled abutments 15° Large	Cover Screw
Ball Attachments (1, 2 & 3 mm)	

The QUAD expansion is performed using a reusable Expansion Tool and Ratchet Torque.

5. INTENDED USE

DenTack QUAD Dental Implants and Prostheses are intended for surgical placement in the maxilla and/or in the mandible to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous jaws utilizing delayed loading, or immediate loading when good primary stability is achieved and with appropriate occlusal loading.

6. PERFORMANCE DATA

A series of performance tests and evaluations were performed to demonstrate that DenTack's Dental Implant System is substantially equivalence with the predicate devices. These tests are:

- a) **Fatigue Test** – This test was conducted according to ISO 14801:2007 standard for *Dentistry –Implants – Dynamic fatigue test for endosseous dental implants* and with accordance to FDA Guidance for *Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments* (dated: May 12, 2004).

Worst case configuration was selected to reflect the most challenging situation for the implant and abutment.

- b) **Surface analysis** – The implant surface was tested using the SEM (Scanning Electron Microscope).
- c) **QUAD Removal after Expansion** – This comparative test was conducted per DenTack protocol, in order to demonstrate that the expandable design does not cause additional damage to the surrounding tissue.
- For the purpose of this test artificial bone was used and a reference legally marketed device for comparison. Both implants were "implanted" in the artificial bone and removed per instructions for use. The evaluation post implant removal showed that both implants performed equally in terms of interaction with the bone.
- d) **Evaluation of Minimal Rotation Torque after Placement and Expansion** – The test was conducted per DenTack protocol, in order to evaluate the minimal rotation torque after QUAD placement and expansion in the artificial bone.
- This evaluation was conducted in comparison to predicate device, simulating the product use per their instructions for use. The tests results found to be very similar and thus equivalent. The QUAD met the acceptance criteria and performed at least as good as or better than the predicate device.
- e) **Partially expanded QUAD Implant Reciprocating Effect Test** –
- The test was conducted per DenTack protocol, in order to demonstrate that the instructions to counterclockwise and clockwise rotation, when the QUAD only partially expanded, do not cause to an additional damage to the surrounding bone or to the implant. The test was conducted in comparison to a legally marketed device with similar instructions for use (counterclockwise rotation when insufficient insertion occurs). The study demonstrated that both the surrounding bone and the implant were not negatively affected by counterclockwise/clockwise rotation and that the QUAD performed similarly to the reference device.
- f) **Biocompatibility** – Biocompatibility was evaluated with accordance to ISO 10993-1 for *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, considering exhaustive extractions and potential biological (cytotoxic) reaction.
- The tests were conducted using final and sterilized products with accordance to above mentioned ISO 10993-1 as well as; ISO 10993-5 for *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* and;



ISO 10993-12 for *Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials*. The chemical and biological tests have not revealed any incompatibility potential or any adverse effect.

- g) Gamma Sterilization Validation** – Sterilization validation was conducted with successful results, using Gamma Irradiation according to VDmax method with accordance to ISO 11137-2 for *Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*, and in conjunction with AAMI TIR 33 (recently revised to: ISO TS 13004).
- h) Steam Sterilization Validation** – Was performed to validate the instructions for steam sterilization provided by DenTack for prosthetic parts that are provided non-sterile and are to be steam sterilized by the user at the clinic. The validation was conducted with accordance to ISO 17665-1:2006, ANSI AAMI ST79:2010 and ANSI AAMI ST77:2013. The validation results supported SAL 10^{-6} . IFU (instructions for use) are in-line with the validation results.
- i) Shelf life validation** – Was performed with accordance to ISO 11607-1 for *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems*. This validation confirmed that the sterility of DenTack's sterile products will be remained for the device shelf life.

All results are supporting DenTack's labeling claims in order to establish substantial equivalency with the selected predicate devices.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

DenTack Implants are manufactured from biocompatible Titanium. Implant surface is treated by an established sand-blasting method.

Restorative components are manufactured with common titanium alloy, stainless-steel and polymers.

The proposed DenTack's Dental Implant System has 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.

Therefore it was concluded that they are substantially equivalent.



Certain differences between subject and predicate devices did not alter the substantial equivalent determination, since they were established by performance testing. The implant expansion was evaluated through tests 'c'-'d' described above. Differences in abutment maximal angulation and connection types were evaluated through fatigue tests under worst case scenario (DenTack's 25° abutment with the narrowest implant OD). Differences between the submission device and the primary predicate with respect to surgical protocol for rotation after partial expansion are supported by the reference predicate K071370 and the comparative partial expansion rotation performance testing. Differences between the submission device and the primary predicate with respect to implant length are supported by the reference predicate K131097.

The comparison of the similarities and differences between QUAD implant and predicated devices are hereby presented in the tables below:

Feature	- Primary Predicate Device - Sargon's 510(k) K981141	- New Device - DenTack's QUAD
Intended Use	For use in either partially or fully edentulous mandibles and maxillae as a final or intermediary abutment for fixed detachable prosthesis and for use in support of free standing restorations with or without the involvement of adjacent dentition.	DenTack Dental Implants and Prosthesis are intended for surgical placement in the maxilla and/or in the mandible to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous jaws utilizing conventional, delayed or immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Patient Population	Edentulous or partially Edentulous individuals	Edentulous or partially Edentulous individuals
Material	Titanium alloy ELI	Titanium
Implant Model	Sargon Immediate Load Implant (expandable)	DenTack QUAD Dental Implants (expandable) for conventional, delayed or immediate load.
Implant Dimensions	Length (mm): 10, 13,16 Diameter (mm): 3.8	Length (mm): 7, 8, 9, 10, 11 Diameter (mm): 3.75, 4.1
Surface	Alumina blasting (grit blasting and then acid etching surface)	Sand Blasting and acid etching

Feature	- Primary Predicate Device - Sargon's 510(k) K981141	- New Device - DenTack's QUAD
Implants Design	Apically expandable root form dental implant.	Apically expandable root form dental implant.
Expansion Mechanism	Screw driver manipulates internal parts until expanded.	Expansion tool is inserted in the implant upper platform and implant is expanded using the ratchet torque.
Sterility	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation
Placement method	Placing the implant immediately after drilling	Placing the implant immediately after drilling
Self-Tapping	Yes	Yes
Connection type	Internal and External hex	Internal hex
Abutment connection	With and without abutment	With abutment
Maximum abutment angle	N/A (Sargon 510(k) refers only to the implant)	25°

Subject	- Reference Predicate Device - Biomet 510(k) K072642	- New Device - DenTack Prostheses
Indications for Use	<p>BIOMET 3i Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained.</p> <p>Restorative Components:</p> <ul style="list-style-type: none"> • Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing. • Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics. • Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant. 	Same indications and clinical purpose

Subject	- Reference Predicate Device - Biomet 510(k) K072642	- New Device - DenTack Prostheses
Items Identification and Description	IPAP462G, Angled abutment 8 mm length 15° angle	Angled Abutment 8.5 mm length 15° angle
	IPAP474G Angled Abutment 11.5 mm length 15° angle	Angled Abutment, large, 11.6 mm length 15° angle
	IPAP462G Angled Abutment (AA) 8 mm length 15° angle. Note that except for the angle, DenTack AA 25° is the same in all respects to the AA-15° and that AA 25° was used as part of the worst case scenario in the fatigue test where it showed good failure resistance.	Angled Abutment 8.5 mm length 25° angle
	Ball Attachment (BA) Similar to Biomet part presented for DenTack's Ball Attachment (BA), dimensions vary according to gingival height.	Ball attachment abutment 3 mm height
		Ball attachment abutment 2 mm height
	OSO20 O-Ring Abutment 2 mm height	Ball attachment abutment 1 mm height
	IGUCA2C Direct Screw Platform 11.0 mm height. *Same as DenTack's	Direct Screw Platform (casting abutment) 11.7 mm height *Made of both Titanium & Plastic. Titanium is gingival contact. The Plastic has no body contact.
Straight Abutment – Similar to Biomet part presented for DenTack's Straight Abutment (SA), dimensions vary according to gingival height.	Straight abutment 1 mm length	
	IAPP454G GingiHue© Post 4 mm height (One representative model among others that vary in gingival height)	Straight abutment 2 mm length
		Straight abutment 3 mm length
		Straight abutment 0.5 mm length
	ICAOO2 Certain® Conical Abutment 4.1mm(D) X 2mm length	Screw retained abutments 1.5 mm length
		Screw retained abutments 2.5 mm length

Subject	- Reference Predicate Device - Biomet 510(k) K072642	- New Device - DenTack Prostheses
	ILPC342U (One representative model among others that vary in gingival height)	Straight Multi-unit abutments 2 mm length Straight Multi-unit abutments 3 mm length Straight Multi-unit abutments 4 mm length
	THA52 EP® Healing Abutment 2 mm length.	Healing caps 2 mm length
	THA53 EP® Healing Abutment 3 mm length	Healing caps 3 mm length
	THA54 EP® Healing Abutment 4 mm length	Healing caps 4 mm length
	<i>N/A – Part of DenTack's implant (designated)</i>	Cover Screw 0.1 mm length
	LAIC1 Impression coping. *Same.	Metal housing 3.3 mm height. *Made of SS
	LAERM Extended range males *Same as DenTacks (Plastic).	Plastic cup 2.7 mm height. *Made of Plastic (Nylon)
	ILPC342U (One representative model among others that vary in gingival height)	Straight Multi-unit Sleeve 10 mm height + Straight Multi-unit Screw 1.8 mm height
Materials	Titanium, Titanium alloy, gold, gold alloy, zirconium, vanadium, stainless steel, polyetheretherketone (PEEK), cobalt chromium alloy, and polyoxymethylene (Delrin)	Titanium alloy, stainless-steel and polymers (nylon)
Sterility	Some are provided sterile and some provided non-sterile and to be sterilized by the user	Non-Sterile (except for the cover screw)
Single Use	Sterile provided: Single use	Single use
Abutment Max. Angle	15°	25°
Connection	Internal and External Hex Connections	Internal Hex Connection



8. CONCLUSIONS

The DenTack's QUAD dental implants and prostheses, which are the subject of this 510(k) submission, are substantially equivalent to the predicate devices cited above. The device met its requirements and labeling claims per its intended use. 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.

Therefore, it was concluded that the overall evaluation of our device performances demonstrates that it is substantially equivalent to the predicate devices.