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

May 6, 2016

Adin Dental Implants Systems Ltd.
c/o Iman Khorshid
CEO, Founder
QRS
Industrial Park Tefen
Tefen 2495900
ISRAEL

Re: K153111
Trade/Device Name: TOUAREG CloseFit™ UNP 2.75mmD
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 31, 2016
Received: April 6, 2016

Dear Iman Khorshid:

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,

for 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

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)*

K153111

Device Name
TOUAREG CloseFit™ UNP 2.75mmD

Indications for Use *(Describe)*

TOUAREG CloseFit™ UNP 2.75mmD implants are indicated to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. For single-stage or two-stage procedures. For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When an one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and thefunctional load is appropriate.
The TOUAREG CloseFit™ UNP 2.75mmDDental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors.

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:

TOUAREG CloseFit™ UNP 2.75mmD Implants

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Date prepared: May 5, 2016

Trade Name: TOUAREG CloseFit™ UNP 2.75mmD

Classification name: Endosseous Dental Implant

Common/usual name: Dental Implant

Product Code: DZE; NHA

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Predicate Devices:

Primary Predicate: Adin Dental Implant Systems Ltd. dental implants Touareg CloseFit™ NP, cleared under 510(k) K140293.

Reference Predicates: Anthogyr SAS' Axiom 2.8 implant cleared under 510(k) K141450 and Adin Dental Implant Systems Ltd. dental implants Touareg CloseFit™, cleared under 510(k) K112585.

Description of the device:

The TOUAREG CloseFit™ UNP 2.75mmD spiral implant system is comprised of a tapered core implant with a spiral tap, with unique tip and triple lead thread design (3x1mm).

The TOUAREG CloseFit™ UNP 2.75mmD spiral implant system offers a unique, strong and solid conical-hex connection.

All Touareg CloseFit™ implants feature the OsseoFix™ surface treatment The TOUAREG CloseFit™ UNP 2.75mmD implant is provided with a diameter of 2.75mm and lengths of 10, 11, 13, 16 and 18 mm.

The TOUAREG CloseFit™ UNP 2.75mmD implants are two piece devices whereas the implant is to be used in combination with cover screws, healing abutments and abutments.

The TOUAREG CloseFit™ UNP 2.75mmD implants, abutments, and abutment fixation screw are made of Ti6AL4V ELI complying with standard ASTM F 136-08- Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

Indications for Use:

TOUAREG CloseFit™ UNP 2.75mmD implants are indicated to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. For single-stage or two-stage procedures. For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and thefunctional load is appropriate.

The TOUAREG CloseFit™ UNP 2.75mmDDental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors.

Substantial Equivalence:

Technological Characteristics

The TOUAREG CloseFit™ UNP 2.75mmD implants have the same intended use as Adin Dental Implant Systems Ltd. TOUAREG NP CloseFit™ Dental Implants, cleared under 510(k) K140293 with the exception of the elimination of the specific indications for the TMA Abutment cleared in the primary predicate K140293 but is not included in the current submission device. Further the indications for the submission device are identical to the reference predicate K141450. The material used for the TOUAREG CloseFit™ UNP 2.75mmD dental implants and abutment (Ti6AL4V ELI), as well as the surface treatment and other manufacturing methods, are identical to Adin's TOUAREG NP CloseFit™ Dental Implants as well as previously cleared Adin's TOUAREG CloseFit™ Dental Implants, cleared under 510(k) K112585. The sterility status of the implant bodies and abutments are identical to Adin's previously cleared TOUAREG NP CloseFit Dental Implants and the previous sterilization validation supports the sterility of the current submission. The available abutment designs are similar to the applicant's own previously cleared dental abutments and the maximum angulation of the abutment is the same as the applicant's own predicate devices as well as supported for substantial equivalence by fatigue test results.

The main differences between the submission device and the primary predicate

are the reduction in implant body diameter for the submission device from 3.0mm to 2.75mm and the inclusion of an 18mm length implant body. The reference predicate Axiom 2.8 Implant K141450 supports the reduction in implant body diameter. The reference predicate K112585 supports the inclusion of a longer implant body.

	Touareg CloseFit™ UNP Dental Implants from Adin Dental Implant Systems Ltd.	**Touareg NP CloseFit™ Dental Implants from Adin Dental Implant Systems Ltd.**	**Axiom® 2.8 Implants from Anthogyr SAS**	**Touareg CloseFit™ Dental Implants from Adin Dental Implant Systems Ltd.**
Predicate		Primary Predicate	Reference Predicate	Reference Predicate
510(k) number		K140293	K141450	K112585
Product Code	DZE	DZE	DZE	DZE
Indications For Use	TOUAREG CloseFit™ UNP 2.75mmD implants	Intended use for Touareg NP CloseFit™ Dental	ANTHOGYR Axiom® implants are intended for use	Touareg CloseFit™ Dental Implants are intended for

	Touareg CloseFit™ UNP Dental Implants from Adin Dental Implant Systems Ltd.	**Touareg NP CloseFit™ Dental Implants from Adin Dental Implant Systems Ltd.**	**Axiom® 2.8 Implants from Anthogyr SAS**	**Touareg CloseFit™ Dental Implants from Adin Dental Implant Systems Ltd.**
	are indicated to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. For single-stage or two-stage procedures. For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When an one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and the functional load is appropriate. The TOUAREG CloseFit™ UNP 2.75mmDDental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors.	Implant System: _ To replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. _ For single-stage or two-stage procedures. _ For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate. _ The Touareg NP CloseFit™ Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors. _ The Trans Mucosal Abutment (TMA) is indicated for multiple-unit, screw-retained	as artificial root structures for replacement of missing teeth. They can be used for fixation of single tooth restorations. ANTHOGYR dental systems are indicated for one-stage or two stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading. Axiom® 2.8 implants are indicated for single replacement of mandibular incisors and lateral maxillary incisors in cases presenting a restricted mesiodistal space. The prosthetic components of the Axiom 2.8 product line are intended to ensure support for single	surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. Touareg CloseFit™ Dental Implants may be mmediately loaded when good primary stability is achieved and with ppropriate occlusal loading.

	Touareg CloseFit™ UNP Dental Implants from Adin Dental Implant Systems Ltd.	**Touareg NP CloseFit™ Dental Implants from Adin Dental Implant Systems Ltd.**	**Axiom® 2.8 Implants from Anthogyr SAS**	**Touareg CloseFit™ Dental Implants from Adin Dental Implant Systems Ltd.**
		restorations, and may be used in combination with an implant level framework design.	crowns only.	
Supplied Sterile	Yes	Yes	Yes	Yes
Re-use	No	No	No	No
Material of Construction	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI
Shape	Screw type	Screw type	Screw type	Screw type
Surface Treatment	OsseoFix™ and anodized	OsseoFix™ and anodized	BCP®	OsseoFix™ and anodized
Length	10, 11.5, 13, 16 and 18 mm	10, 11.5, 13 and 16 mm	10, 12, and 14 mm	8, 10, 11.5, 13, 15 and 18 mm
Thread Diameter	2.75 mm	3.0 mm	2.8 mm	3.5, 4.3 and 5.0 mm
Abutment	Straight and up to 15°	Straight and up to 15°	Straight and up to 23°	Straight and up to 15°
Material of Construction of Abutments	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI

Non-Clinical Performance Data

Fatigue test was performed according to ISO 14801:2007 on the TOUAREG CloseFit™ UNP 2.75mmD dental implants and showed equivalence to the predicate devices.

Clinical Performance Data

No clinical performance data is provided in this submission.

Conclusion:

The evaluation of the TOUAREG CloseFit™ UNP 2.75mmD dental implants may therefore be considered substantially equivalent to its predicate device.