K112585

MAY 2 4 2012



## Revised 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

### Submitter Information

Adin Dental Implants Systems Ltd

Industrial Zone Alon Tavor

P.O. Box 1128

Afula 18550

Israel,

Tel: (+972-4-6426732, Fax: (+972) 4-6426733

Establishment Reg. Number: 3007518363

### Submission contact person:

Mrs. Yana Prus-Galynsky

Quality and Regulatory Director

Tel: (+972-4-6426732 ext. 159, Fax: (+972) 4-6426733

### Submission Date:

3rd of April, 2012

### Device Classification

| | |
|---|---|
| **Trade/Proprietary Device Name:** | Touareg CloseFit™ Dental Implant |
| **Common name:** | Endosseous Dental Implant 21 CFR 872.3640 |
| **Product Code:** | DZE (subsequent code NHA) |
| **Classification Name:** | Endosseous Dental Implant |
| **Classification Regulation:** | 21 CFR §872.3640 (subsequent 21 CFR872.3630) |
| **Classification Panel:** | Dental Devices |
| **Regulatory Class:** | II |

### Identification of Legally Marketed Predicate Devices

| | |
|---|---|
| Adin Dental Implants System - | K081751 |

**Device Description**

Touareg CloseFit™ Dental Implants are threaded, root-form dental implants intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.
The Touareg CloseFit™ Dental Implants are similar in design to the Touareg Dental Implant cleared under Adin Dental Implant System, K081751. The predicate internal connection was changed to internal hex (hexagonal) Morse tapered connection. In addition, dental implant name was changed from Touareg Dental Implants to the Touareg CloseFit™ Dental Implants to extend Touareg Implants family's product line, and surface treatment name was changed to OsseoFix™ due to marketing reasons only. Also, lengths and diameters were added - implants are now provided in diameter of 4.3mm, and lengths of 15.0 mm and 18.0 mm.

**Intended Use of Device**

Touareg CloseFit™ Dental Implants are intended for 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 immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

**Brief Discussion and conclusions drawn from the Non-Clinical Tests Submitted**

For a determination of substantial equivalence, the following analysis and bench performance test was performed on Subject Devices ahd Predicate Devices:

- Fatigue testing according to ISO 14801:2007 "Dentistry-Implants-Dynamic fatigue test for endosseous dental implants" was done with angled abutments to demonstrate the design changes did not change the fatigue properties. Fatigue testing also demonstrated that this system meets its predefined acceptance criteria and performs in accordance with its intended use. The fatigue properties of the new design are similar to those of the predicate device.

**Substantial Equivalence Statement**

Based on the performance testing results, and compliance to performance standards, it is Adin Dental Implant Systems Ltd opinion that the proposed Touareg CloseFit™ Dental Implant is substantially equivalent in terms of design, functional features to the unmodified Adin Dental Implants System (legally marketed predicate device)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mrs. Yana Prus-Galynsky
Quality and Regulatory Director
Adin Dental Implants Systems Ltd
Industrial Zone Alon Tavor
P.O. Box 1128
Afula
ISRAEL 18550

MAY 24 2012

Re: K112585
Trade/Device Name: Touareg CloseFit™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 23, 2012
Received: May 23, 2012

Dear Mrs. Prus-Galynsky:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K112585

Device Name: Touareg CloseFit™ Dental Implant System

Indications for Use:

Touareg CloseFit™ Dental Implants are intended for 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 immediately loaded when good primary stability is achieved and with appropriate occlusal loading

Prescription Use ___✓____ (21 CFR 801 Subpart D) AND/OR 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)
Center for Devices and Radiological Health / CDRH



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112585