July 8, 2022

Adin Dental Implants Systems Ltd.
% Tali Hazan
RA Consultant
Talmed Ltd
Ramot-Naftali, M.P. Upper Galilee 1383000
ISRAEL

Re: K212775
Trade/Device Name: Adin Short Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: June 4, 2022
Received: June 9, 2022

Dear Tali 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212775

Device Name
Adin Short Implants

Indications for Use *(Describe)*
Adin Dental Implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in fully or partially edentulous patients in order to restore a patient's chewing function. Adin Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Adin short implants are to be used only with straight abutments.

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 ADIN SHORT IMPLANTS
# K212775

**DATE PREPARED:** JULY 07, 2022

## 1. 510(K) OWNER NAME

Adin Dental Implants Systems Ltd.
Alon Tavor Industrial Zone P.O. Box 1128, Afula 1811101, Israel
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**Contact person name:** Tali Hazan, RA Consultant, Talmed Ltd.
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Email: tali.hazan@talmed.co.il.

## 2. DEVICE NAME

**2.1 Device's Trade name:** Adin Short Implants
**2.2 Classification Name:** Implant, Dental, Endosseous, Root-Form
**2.3 Device's Common Name:** Endosseous dental implant
**2.4 Regulation Number:** 21 CFR 872.3640
**2.5 Class:** II
**2.6 Product Code:** DZE

## 3. PREDICATE DEVICES

Adin Short Implants are substantially equivalent to the following Predicate Devices:

**3.1 Primary predicate device:** Adin's Dental Implants System, cleared under 510(k) number K081751 on December 19, 2008.

**3.2 Reference device:** Adin's *Touareg CloseFit™ Dental Implant System*, cleared under 510(k) number K112585 on May 24, 2012.

**3.3 Reference device:** MIS's *Short Implants*, cleared under 510(k) number K103089 on September 15, 2011.

**3.4 Reference device:** Blue Sky Bio's Dental *Implant System*, cleared under 510(k) number K102034 on April 19, 2011.

## 4. DEVICE DESCRIPTION

Adin Short Implants are self-tapping root-form two-piece screw type dental implants, indicated for use in Surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.
Adin's Short Implants are provided in 6.25mm length and 4.2mm, 5.0 mm, and 6.0mm diameters, as follows:
The Touareg™-S and Swell™ short implants with internal hexagon in 6.25mm length are available in diameters of 4.20mm, 5.0 mm and 6.0mm. The implants surface treatment is AB/AE (Alumina Oxide Blast/Acid Etched) for both of them. The Touareg-S short implant has a spiral tapered design and the Swell™ short implant has a straight, parallel walled, slightly tapered V-shape thread design.
The Touareg-OS short implant with internal hexagon in 6.25mm length is available in diameters of 4.20mm, 5.0mm and 6.0mm. The implants surface treatment is OsseoFix™ (Calcium Phosphate). The Touareg™-OS short implant has the same design as the Touareg™-S. The only difference between them is the surface treatment.

As two-piece devices, like the predicate devices, Adin Short Implants are to be used in combination with cover screws, healing caps and straight abutments.
The Adin Short Implants are made of Titanium 6AL-4V-ELI Alloy, complying with ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.

Body contact materials were evaluated for biocompatibility in accordance with FDA's Guidance document for *Use of ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process*, dated September 4, 2020 together with ISO 10993-1:2018 and ISO 7405:2018 standards.

## 5. INTENDED USE

Adin Dental Implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in fully or partially edentulous patients in order to restore a patient's chewing function. Adin Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Adin short implants are to be used only with straight abutments.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Adin Short Implants have the same intended use as the MIS short implants that were cleared under 510(k) K103089, Adin's Touareg™-S and Swell™ implants cleared under 510(k) number K081751, Adin's Touareg CloseFit™ K112585 and Blue Sky Bio's Dental Implant System cleared under 510(k) number K102034 (excluding the one-piece implant model).

Adin Short Implants are available in three models: Touareg™-S, Touareg™-OS and Swell™. Two types of surface treatments are utilized for the short implants: AB/AE (Alumina Oxide Blast/Acid Etched), also used for Touareg™-S and Swell™ cleared implants and; OsseoFix™ (Calcium Phosphate), as cleared under 510(k) K112585, for Adin's Touareg CloseFit™ Dental Implant System.

For the purpose of substantial equivalency, the Touareg™-S, Touareg™-OS and Swell™ short implants are supported by Adin's 510(k) K081751 while the Touareg™-OS is further supported by 510(k) K112585 only to cover the OsseoFix™ surface treatment method. The MIS short implants cleared under K103089 support the 6.25mm length dimension of all Adin Short Implants' models. The Blue Sky Bio Dental Implant System cleared under 510(k) K102034, was used for additional support of Adin's Swell™ pull-out force.

The subject device and its predicate devices have the same technology and basic performance characteristics. Except for the length dimensions, the design of the subject Touareg-S™ and Swell™ short implants are exactly the same as the cleared Touareg-S™ and Swell™ implants. The subject and predicate devices are manufactured from the same biocompatible Titanium alloy and undergo same machining, surface treatment and sterilization processes.
It was therefore concluded that Adin Short Implants are substantially equivalent to the predicate devices.

## 7. NON-CLINICAL PERFORMANCE DATA

A series of safety and performance tests and evaluations were performed to demonstrate that Adin Short Implants do not raise any new issues of safety and effectiveness to support substantial equivalence with the predicate devices. These evaluations included:

**a) Pull-Out Testing**

The test was performed to determining the axial pull-out strength of the Adin Short Implants as compared to the proposed predicate devices: MIS short implants (K103089) for the Touareg™-S and OS short implants and Blue Sky Bio Dental Implant System (K102034) for the Swell™ short implant. The test was performed according to the requirements of ASTM F543 *Standard Specification and Test Methods for Metallic Medical Bone Screws* in comparison with legally marketed device.

**b) Comparative Bone to Implant Contact Surface Area Analysis–**

Contact surface area was analyzed in comparison to both legally marketed devices (MIS short implants and Blue Sky Bio Dental Implant System, cleared under 510(k) K103089 and K102034, respectively), at worst case implant variation.

**c) Comparative Surface Analysis Before Surface Treatment –**

Implant actual surface area before surface treatment was compared to both legally marketed devices (MIS short implants and Blue Sky Bio Dental Implant System, cleared under 510(k) K103089 and K102034, respectively), at worst case implant variation.

**d) Biocompatibility** –

Biocompatibility tests were conducted in accordance with FDA Guidance for *Use of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, September 4, 2020, and; ISO 10993-1 for *biological evaluation* and; ISO 7405:2018 for *evaluation of medical devices used in dentistry. In-vitro* Cytotoxicity test of each surface treatment type, using the ISO Elution Method was conducted as well as Pyrogenic Material-Mediated and chemical extractions.

ISO 10993-5, ISO 10993-11 and ISO 10993-18 were used for the Cytotoxicity, Pyrogen Material-Mediated and chemical extractions, respectively.

Tests have been conducted using representative final implants with both surface treatments which went through Adin's entire production process, including packaging and sterilization (Gamma irradiation).

**e) Surface Analysis After Surface Treatment –**

The implants' surface after surface treatments was tested for each surface treatment type (AB/EA and OsseoFix™) using the SEM/EDS (Scanning Electron Microscope / Energy Dispersive X-ray Spectroscopy) which are valid, conventional and known methods to evaluate the quality of the treated surface area.

**f) Gamma sterilization validation –**

Sterilization validation was conducted with successful results, using Gamma Irradiation according to VDmax method in accordance with ISO 11137-2 for Sterilization of health care products Radiation – Part 2: Establishing the sterilization dose in conjunction with ISO/TS 13004, in order to assure SAL (Sterility Assurance Level) of $10^{-6}$. The sterilization validation includes both the implants and the cover screw.

**g) Shelf-life validation –**

Shelf-life validation was performed in accordance with ISO 11607-1 for Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems standard.

This validation confirmed that the sterility of Adin's sterile products will remain throughout the device shelf life.

**h) MR Environment Condition –**

Non-clinical worst-case MRI review was performed to evaluate the metallic Adin Short Implants in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices"*, Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

All performance tests' results and worst-case MRI review, support Adin's labeling claims in order to establish substantial equivalency with the selected predicate devices.

## 8. SUBSTANTIAL EQUIVALENCE

Adin Short Implants are substantial equivalent to the predicate devices selected in terms of indication for use, technology, performances, design, place of use, patient population and nature of body contact.

The Substantial equivalent decision was received based on the following comparison with the predicate devices:

| Feature | Adin Short Implants (Touareg-S™, Touareg™-OS, Swell™)<br><br>- Subject Device - | Adin's Touareg-S and Swell™ Dental Implants, cleared under K081751<br><br>- Primary Predicate Device - | Adin's CloseFit™ Dental Implant System, cleared under K112585<br><br>- Reference Device - | MIS's MIS Short Implants, cleared under K103089<br><br>- Reference Device - | Blue Sky Bio's Dental Implant System, cleared under K102034<br><br>- Reference Device - |
|---|---|---|---|---|---|
| **510(k) number** | K212775 | K081751 | K112585 | K103089 | K102034 |
| **Classification** | **Class:** II<br>**Product code:** DZE<br>**Regulation No.:** 872.3640 | **Class:** II<br>**Product code:** DZE (primary) NHA (secondary)<br>**Regulation No.:** 872.3640 | **Class:** II<br>**Product code:** DZE (primary), NHA (secondary)<br>**Regulation No.:** 872.3640 | **Class:** II<br>**Product code:** DZE (primary), NHA (secondary)<br>**Regulation No.:** 872.3640 | **Class:** II<br>**Product code:** DZE (primary), NHA (secondary)<br>**Regulation No.:** 872.3640 |
| **Indications For Use** | Adin Dental Implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in fully or partially edentulous patients in order to restore a patient's chewing function. Adin Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Adin short implants are to be used only with straight abutments. | Adin 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. Adin Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. | 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 | MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal | Intended Use for Two-Piece Implant Systems:<br>• For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For single tooth or multiple unit prosthesis<br>• For single stage or two stage surgical procedure<br>• For immediate placement and immediate function when multiple units are splinted |

| Feature | Adin Short Implants (Touareg-S™, Touareg™-OS, Swell™)<br><br>- Subject Device - | Adin's Touareg-S and Swell™ Dental Implants, cleared under K081751<br><br>- Primary Predicate Device - | Adin's CloseFit™ Dental Implant System, cleared under K112585<br><br>- Reference Device - | MIS's MIS Short Implants, cleared under K103089<br><br>- Reference Device - | Blue Sky Bio's Dental Implant System, cleared under K102034<br><br>- Reference Device - |
|---|---|---|---|---|---|
| | | | with appropriate occlusal loading. | load is appropriate. MIS short implants are to be used only with straight abutments. | and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. Multiple units may be splinted with a bar. In edentulous cases restored with a fixed prosthesis, four or more implants must be used. |
| **Patient population** | Edentulous or partially edentulous patients | Edentulous or partially edentulous patients | Edentulous or partially edentulous patients | Edentulous or partially edentulous patients | Edentulous or partially edentulous patients |
| **Sterility** | Sterile using Gamma Irradiation | Sterile using Gamma Irradiation | Sterile using Gamma Irradiation | Sterile using Gamma Irradiation | Sterile using Gamma Irradiation |
| **Nature of body contact** | Implant in bone/tissue contact for long term duration (>30 d) | Implant in bone/tissue contact for long term duration (>30 d) | Implant in bone/tissue contact for long term duration (>30 d) | Implant in bone/tissue contact for long term duration (>30 d) | Implant in bone/tissue contact for long term duration (>30 d) |
| **Prescription or Over-the-Counter (OTC)** | Prescription | Prescription | Prescription | Prescription | Prescription |
| **Single use** | Yes | Yes | Yes | Yes | Yes |
| **Operation Principle** | Single or Two-Stages procedure (immediate or delayed loading) | Single or Two-Stages procedure (immediate or delayed loading) | Single or Two-Stages procedure (immediate or | Single or Two-Stages procedure (immediate or | Single or Two-Stages procedure |

| Feature | Adin Short Implants (Touareg-S™, Touareg™-OS, Swell™)<br><br>- Subject Device - | Adin's Touareg-S and Swell™ Dental Implants, cleared under K081751<br><br>- Primary Predicate Device - | Adin's CloseFit™ Dental Implant System, cleared under K112585<br><br>- Reference Device - | MIS's MIS Short Implants, cleared under K103089<br><br>- Reference Device - | Blue Sky Bio's Dental Implant System, cleared under K102034<br><br>- Reference Device - |
|---|---|---|---|---|---|
| | | | delayed loading) | delayed loading) | (immediate or delayed loading) |
| **Placement Method** | Placing the implant in the jaw bone immediately after drilling | Placing the implant in the jaw bone immediately after drilling | Placing the implant in the jaw bone immediately after drilling | Placing the implant in the jaw bone immediately after drilling | Placing the implant in the jaw bone immediately after drilling |
| **Self-Tapping** | Yes | Yes | Yes | Yes | Yes |
| **Implant Material** | Titanium Alloy – 6Al-4V-ELI | Titanium Alloy – 6Al-4V-ELI | Titanium Alloy – 6Al-4V-ELI | Titanium Alloy – 6Al-4V-ELI | Titanium Alloy – 6Al-4V |
| **Biocompatibility** | Biocompatible | Biocompatible | Biocompatible | Biocompatible | Biocompatible |
| **Shape** | Screw type | Screw type | Screw type | Screw type | Screw type |
| **Connection** | Internal hexagon | Internal hexagon | Conical hexagon | Internal hexagon | Internal hexagon with taper, Internal Square with taper (anti-rotational feature) |
| **Surface Treatment** | AB/AE and OsseoFix™ | AB/AE | OsseoFix™ Calcium Phosphate | Sand blasting & Acid Etching | Blasted with resorbable medium or Aluminum Oxide and Acid Etched |
| **Implanted Length** | 6.25 mm | 8, 10, 11.5, 13, 16, 18 mm | 8, 10, 11.5, 13, 16, 18 mm | 6.0 mm | 6-16 mm |
| **Outer Diameter (OD)** | 4.2, 5, 6 mm | Swell Implant Model: 3.30, 3.75, 4.2, 5, 6mm<br>Touareg-S Model: 3.5, 3.75, 4.2, 5, 6mm | 3.5, 3.75, 4.2, 5, 6mm | 4.2, 5, 6 mm | 3.25-5.0 mm |
| **Abutment Angulation** | Straight abutment only | Straight and up to 25° | Straight and up to 25° | Straight abutment only | Straight and up to 30° |
| **Packaging (Microbial Barrier)** | Sterile barrier Protective Tube | Sterile barrier Protective Tube | Sterile barrier Protective Tube | Sterile barrier Protective Tube | Sterile barrier |

| Feature | Adin Short Implants (Touareg-S™, Touareg™-OS, Swell™)<br><br>- Subject Device - | Adin's Touareg-S and Swell™ Dental Implants, cleared under K081751<br><br>- Primary Predicate Device - | Adin's CloseFit™ Dental Implant System, cleared under K112585<br><br>- Reference Device - | MIS's MIS Short Implants, cleared under K103089<br><br>- Reference Device - | Blue Sky Bio's Dental Implant System, cleared under K102034<br><br>- Reference Device - |
|---|---|---|---|---|---|
| **Shelf-Life** | 5 years | 5 years | 5 years | Information not available | Information not available |

**Substantial Equivalence Discussion:**

The proposed Adin Short Implants have same indications for use, technological characteristics, mode of operation and, performance specifications as the above identified predicate devices. The proposed device utilizes same intended use as the predicate devices and is placed using the same methodology as all 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. Similarities and differences were addressed by Adin. It can be seen that certain differences presented in the comparison table, are all within the range of one or more predicate device(s).
For the purpose of the comparison with Adin Short Implants, several aspects were removed from the indications for use of the Blue Sky Bio dental implant System, since are referring to Blue Sky Bio's one-piece model, two-piece narrow implants, angled abutments, as well as device adjustments to other companies products. These features are not included in any of Adin's claims within this submission and therefore, these parts were removed from the indications for use column of the comparison table.
Blue Sky Bio's implants served only for the purpose of comparing the pull-out force, surface area and bone-to-implant (BIC) measurements. It can be seen from the comparison table that this implant, like the other predicates, has the same or highly similar technological characteristics. It has a similar material, screw type shape, similar dimensions and internal hexagon connection. Some minor differences do not raise new questions of safety and effectiveness.

Therefore, it was concluded that Adin Short Implants and the predicate devices are substantially equivalent.

## 9. CONCLUSIONS

Adin Short Implants, which are the subject of this 510(k) Submission, are substantially equivalent to the predicate devices cited above. The device has 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 as safe and as effective as the predicate devices and therefore substantially equivalent.