March 23, 2026

Adin Dental Implant Systems Ltd.
℅ Tal Bresler Stramer
Consultant
OrbitRA
325 Betty Ann Drive
Toronto, M2R 1B4
CANADA

Re: K252031
Trade/Device Name: Adin Long Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 18, 2026
Received: February 19, 2026

Dear Tal Bresler Stramer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K252031

Device Name
Adin Long Dental Implant System

Indications for Use *(Describe)*
The Adin Long Dental Implant System is intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in fully or partially edentulous patients. The implants are intended for multi-unit, full-arch, screw-retained prosthetic restorations and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Adin Touareg-OS Zygomatic Dental Implants are intended for placement in the zygomatic bone in patients with severe atrophic maxilla; they may be used with implant-level framework designs with 45° to 60° angulation.

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'S LONG DENTAL IMPLANT SYSTEM

Date Prepared: March 23, 2026

510(K) OWNER NAME

Adin Dental Implants Systems Ltd.
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DEVICE NAME

Common/Usual Name: Adin Long Dental Implant System
Proprietary/Trade name: Adin Long Dental Implant System
Classification: Adin Long Dental Implant System has been classified as **Class II** devices under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
Implant, Endosseous, Root-Form	DZE (Primary)	872.3640	Dental
Abutment, Implant, Dental, Endosseous	NHA (Secondary)		

PREDICATE DEVICES

Adin's Long Dental Implant System is substantially equivalent to the following Predicate Devices:

- **Primary Predicate Device:** Noris Medical Zygomatic Dental Implants System, cleared under 510(k) number K151909 on April 8, 2016.
- **Reference Device:** Noris Medical Zygomatic Dental Implants System's multi-unit abutment, cleared under 510(k) number K210356 on January 2, 2022.
- **Reference Device:** Adin Short Implants, cleared under 510(k) number K212775 on June 8, 2022.
- **Reference Device:** NobelZygoma 0° abutments, cleared under 510(k) number K161598 on February 15, 2017.
- **Reference Device:** UniFit Dental Implant System, cleared under 510(k) number K223714 on December 29, 2023.

DEVICE DESCRIPTION

Adin Long Dental Implant System is an extension of previously cleared dental implant devices, designed to expand the product offering and provide additional options for dental restoration procedures. Specifically, this submission seeks marketing clearance for the following implants and abutments:

(1) Adin Touareg™-OS Zygomatic Dental Implants:	• Outer diameter of 4.2 mm • Available Lengths: 35.0mm, 37.5mm, 40.0mm, 42.5mm ,47.5mm, 50.0mm, 52.5mm and 55.0mm.
(2) Adin Long Dental Implant System -RS TMA™:	• Connection: RS • Diameter: 4.9 mm • Available Configurations (Angle / Gingival Height): • 45° / 4 mm • 52° / 5 mm • 60° / 5 mm

ADIN TOUAREG™-OS ZYGOMATIC DENTAL IMPLANTS:

Adin Touareg™-OS Zygomatic dental implants is a threaded, root-form dental implants made of biocompatible Ti-6Al-4V ELI alloy complying with ASTM F136-13(2021)e1 – "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications" and ISO 5832-3:2021 "Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy".

Adin Touareg™-OS Zygomatic Dental Implants are used for surgical placement through the maxillary arch and anchored in the zygomatic bone to provide support for prosthetic devices such as artificial teeth to restore the patient's chewing function in edentulous or partially edentulous patients only with severe atrophic maxilla.
Adin Touareg™-OS Zygomatic Dental Implants are intended for extra-maxillary extra-sinus procedures, and their use is limited to ZAGA-4 extra-maxillary implant placement.
The device is intended to be used under the following clinical conditions and surgical parameters:

- Multi-unit reconstruction (TMA), with a rigid splinting of minimum two implants.
- For an edentulous/full mouth restoration, should be used together with at least two standard implants.
- It should be used only in patients with severe atrophic maxilla.
- Extra-maxillary extra-sinus procedures intended to be anchored in the zygoma bone
- One stage or two stage surgical operation.
- Immediate loading (function) is applicable provided that stability requirements are satisfied.

All Touareg™-OS Zygomatic implants have OsseoFix™ surface treatment which was previously cleared under Adin's 510(k) K212775 for Adin's legally marketed Adin Short Implants and remained unchanged since these clearances.

ADIN TOUAREG™-OS ZYGOMATIC IMPLANTS – RS TMA™

The TMA™ system is indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design.
Adin Touareg™-OS Zygomatic implants are intended for TMA in combination with a rigid splinting of a minimum of 2 conventional dental implants.
Screw-retained abutments are made of titanium alloy 6Al-4V ELI complying with ASTM F136-13 and ISO 5832-3:2021 - Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
The TMA system is used to elevate seating platform of restoration when restoration at implant level is not indicated or practical due to the depth or emergence angle of the implant.
The Adin Touareg™-OS Zygomatic Implants - RS Angled TMA™ (45°, 52°, 60°) are only intended for use with the proposed Adin Touareg™-OS Zygomatic Dental Implants.

INTENDED USE

The Adin Long Dental Implant System is intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in fully or partially edentulous patients. The implants are intended for multi-unit, full-arch, screw-retained prosthetic restorations and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Adin Touareg-OS Zygomatic Dental Implants are intended for placement in the zygomatic bone in patients with severe atrophic maxilla; they may be used with implant-level framework designs with 45° to 60° angulation.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Adin Long Dental Implant System has the same intended use as the cleared predicate Noris Medical Zygomatic Dental Implants System, cleared under 510(k) number K151909. Both systems are intended to provide endosseous support for prosthetic devices to restore patient's chewing function in the upper jaw of edentulous or partially edentulous patients. Both devices are intended for extra-maxillary, extra-sinus surgical procedures and enable a one-stage or two-stage surgical operation. In addition, both systems support multi-unit, screw-retained restoration with 45° to 60° angulated abutments. The predicate device was cleared with a 45° abutment. The 52° and 60° angled abutment options were subsequently cleared under the Noris Medical Zygomatic Dental Implant System (K210356) reference device.
Both the subject and predicate devices utilize a Resorbable Blast Media (RBM) surface treatment applied to titanium implants to create a moderately rough surface intended to support osseointegration.
The subject device incorporates Adin's proprietary OsseoFix™ calcium phosphate RBM surface treatment, which uses calcium phosphate-based resorbable media. This surface treatment has been previously cleared in other Adin implant systems (K212775).

PERFORMANCE DATA (NON-CLINICAL)

Non-clinical data provided in this submission in support of a determination of substantial equivalence includes:

BIOCOMPATIBILITY:

Assessments regarding biological compatibility were performed according to ISO 10993-1 and to the FDA Guidance document "Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016". Representative samples of the worst-case devices were subjected to the following testing:

- Cytotoxicity: AAMI ANSI ISO 10993-5: 2009 (R) 2014 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- USP Rabbit Pyrogen Study: 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

The results of the testing demonstrated that the device materials are biocompatible for the intended use.

STERILIZATION VALIDATION:

Sterilization: Gamma sterilization validation was conducted in accordance with ISO 11137-2:2013 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 using VDmax 20kGy.

BACTERIAL ENDOTOXINS

Bacterial endotoxin testing was performed using the Kinetic Turbidimetric Limulus Amebocyte Lysate (LAL) method in accordance with USP <85> by a qualified third-party laboratory. The acceptance criterion was ≤ 20 EU/device, consistent with USP <161> and FDA guidance *"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."*

Periodic LAL endotoxin testing is performed as part of routine quality control to ensure continued compliance with the specified endotoxin limits.

SHELF LIFE

Accelerated shelf-life testing was conducted on the worst-case packaged device configuration in accordance with ISO 11607-1 and ISO 11607-2 to support a five (5) year shelf life. Packaging integrity and sterility evaluations following accelerated aging demonstrated that the sterile barrier system maintains integrity and sterility throughout the labeled shelf life.

CLEANING AND REPROCESSING VALIDATION:

Adin Trans Mucosal Abutments (TMAs) are provided non-sterile for single use and must be cleaned and steam sterilized prior to clinical use according to the instructions provided in the device's Instructions for Use (IFU). Cleaning and steam sterilization procedures were validated in accordance with applicable standards and FDA guidance, including ISO 17664, AAMI TIR12, AAMI TIR30, and the FDA guidance document *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."* The validated cleaning process demonstrated effective removal of organic residues and microbial contamination.
Cleaning and steam sterilization validation previously reviewed by FDA under K223714 was leveraged, as the subject devices utilize the same materials, manufacturing processes, and reprocessing methods.

FATIGUE TESTING

Comparative fatigue testing was performed on the subject device and the predicate device (K151909) to evaluate mechanical performance under worst-case conditions. Testing was conducted using a modified ISO 14801 setup consistent with FDA guidance for endosseous dental implants and adapted to simulate the ZAGA-4 extra-maxillary clinical configuration.

The evaluation assessed the fatigue performance of the zygomatic implant when used with a 60° angled abutment with 5 mm gingival height under worst-case loading conditions, including 10° uncorrected angulation and simulated bone resorption. A minimum of twelve specimens per system were tested using identical methods and loading configurations to enable direct comparison. Results demonstrated comparable fatigue performance between the subject and predicate devices.

MRI COMPATIBILITY

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., 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 to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The 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.

PERFORMANCE DATA (CLINICAL)

The company retrospectively collected real-world data (RWD) to evaluate the clinical performance of the subject system, including the use of angled multi-unit abutments greater than 30°, and compared outcomes to publicly available data for the predicate device (Noris Medical Multi-Unit systems; K151909 and K210356). Records from 37 patients (10 females, 27 males; age range 45–75 years, mean 58.1 ± 8.2) were reviewed. Follow-up ranged from 6 to 22 months (mean 10.4 ± 3.8 months).
One patient (2.7%) was excluded due to loss to follow-up before 6 months. The final analysis population included 36 patients with 92 multi-unit abutments (72 with 60° angulation). All cases involved extra-sinus placement.
Primary effectiveness was defined as implant and angled abutment (45°–60°) success at ≥ 6 months post-loading. In the 36-patient cohort (92 abutments), a 100% success rate was observed, with stable implants, functional abutments, favorable soft tissue healing, and no reported device-related adverse events. Available clinical evaluations did not indicate evidence of evidence of infection, inflammation or fistula.
A post hoc subgroup analysis of patients with ≥ 12 months follow-up (16 patients; 40 abutments) also demonstrated a 100% success rate with no reported adverse events or prosthetic complications.

SUBSTANTIAL EQUIVALENCE OF ADIN'S ADIN LONG DENTAL IMPLANT SYSTEM WITH PREDICATE DEVICE

Table 1 - Adin Touareg™-OS Zygomatic Implants comparison

Feature	Adin Long Dental Implant System – Adin Touareg™-OS Zygomatic Implants - Subject Device -	Noris Medical Zygomatic Denta Implants System - Primary Predicate Device -	Adin Short Implants (Touareg™-OS) - Reference Device -	Equivalence Discussion
510(k) number	K252031	K151909	K212775	NA
Indications For Use	The Adin Long Dental Implant System is intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in fully or partially edentulous patients. The implants are intended for multi-unit, full-arch, screw-retained prosthetic restorations and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Adin Touareg-OS Zygomatic Dental Implants, intended for placement in the zygomatic bone in patients with severe atrophic maxilla; may be used with implant-level framework designs with 45° to 60° angulation.	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.	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.	Similar, for subject device and primary predicate device. (K151909)
Patient population	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Same

Feature	Adin Long Dental Implant System – Adin Touareg™-OS Zygomatic Implants - Subject Device -	Noris Medical Zygomatic Denta Implants System - Primary Predicate Device -	Adin Short Implants (Touareg™-OS) - Reference Device -	Equivalence Discussion
Sterility	Sterile using Gamma Irradiation	Sterile using Gamma Irradiation	Sterile using Gamma Irradiation	Same
Nature of body contact	bone/tissue for long term duration (>30d)	bone/tissue contact for long term duration (>30d)	bone/tissue contact for long term duration (>30d)	Same
Prescription or Over-the-Counter (OTC)	Prescription	Prescription	Prescription	Same
Single use	Yes	Yes	Yes	Same
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 delayed loading)	Same
Placement Method	Placing the implant in the upper jawbone immediately after drilling	Placing the implant in the upper jawbone immediately after drilling	Placing the implant in the jawbone immediately after drilling	Same
Implant Material	Titanium Alloy 6Al-4V-ELI	Titanium Alloy 6Al-4V-ELI	Titanium Alloy 6Al-4V-ELI	Same
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Same
Shape	Screw type	Screw type	Screw type	Same
Connection	Internal hex	Internal hex	Internal hex	Same as primary predicate device
Surface Treatment	OsseoFix™ Calcium Phosphate	RBM (Resorbable blast media)	OsseoFix™ Calcium Phosphate	Identical as reference device
Length	35-55mm	35-57.5 mm	6.25 mm	Similar, the subject device is within the length range of the primary predicate device
Outer Diameter (OD)	4.2mm	4.2mm	4.2, 5, 6mm	Same
Shelf-Life	5 years	5 years	5 years	Same

Table 2 - Adin RS TMA™ comparison:

Feature	Adin Touareg™-OS Zygomatic implants – RS TMA™ - Subject Device -	Noris Medical Zygomatic Dental Implants System - Multi unit 45° - Primary Predicate Device -	Noris Medical Zygomatic Dental Implants System Multi unit - Reference Device -	Nobel Biocare's NobelZygoma 0° Abutments - Reference Device -	Equivalence Discussion
510(k) number	K252031	K151909	K210356	K161598	---
Indications For Use	The Adin Long Dental Implant System is intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in fully or partially edentulous patients. The implants are intended for multi-unit, full-arch, screw-retained prosthetic restorations and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Adin Touareg-OS Zygomatic Dental Implants are intended for placement in the zygomatic bone in patients with severe atrophic maxilla; they may be used with	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.	NobelZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Same. Although primary device doesn't specifically refer to the Multi Unit- it is included as part of the system of K151909. Additionally, the primary device includes a Multi unit of 45^0, this is bridges by reference device K210356 which include Multi units 52^0-60^0 .

Feature	Adin Touareg™-OS Zygomatic implants – RS TMA™ - Subject Device -	Noris Medical Zygomatic Dental Implants System - Multi unit 45° - Primary Predicate Device -	Noris Medical Zygomatic Dental Implants System Multi unit - Reference Device -	Nobel Biocare's NobelZygoma 0° Abutments - Reference Device -	Equivalence Discussion
	implant-level framework designs with 45° to 60° angulation.				
Patient population	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Same
Abutment and it's screw materials	Titanium Alloy 6Al-4V-ELI	Titanium Alloy 6Al-4V-ELI	Titanium Alloy 6Al-4V-ELI	Titanium Alloy 6Al-4V-ELI	Same
Angulated Abutment's Gingival Height (GH)	45° abutment**:** 4 mm 52°, 60° abutment**:** 5 mm	45° abutment: 2 mm	45° abutment: 3, 4, 5mm 52°, 60° abutment**:** 2mm	45° abutment: 6, 8, 10mm 60° abutment: 6, 8mm	Similar, within range of the primary predicate and reference devices K210356 and K161598
Compatible Implant-abutment	Internal Hex	Internal Hex	Internal Hex	Internal Hex	Same as primary predicate and reference devices
Sterility	Supplied non-sterile. Steam sterilized before use	Supplied non-sterile. Steam sterilized before use	Supplied non-sterile. Steam sterilized before use	Supplied sterile	Same as primary predicate and reference devices (excluding K161598)
Single use	Yes	Yes	Yes	Yes	Same