Noris Medical Ltd.
Biatrina Shidlovsky
Senior Regulatory Affairs Expert
8 Hataasia St.
Nesher, 3688808
ISRAEL

February 11, 2025

Re: K241462
Trade/Device Name: LONGY Implant and LONGY-N Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: December 29, 2024
Received: January 13, 2025

Dear Biatrina Shidlovsky:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241462

Device Name
LONGY Implant and LONGY-N Implant

Indications for Use *(Describe)*
The Noris LONGY and LONGY-N implants are indicated for splinted restorations in the maxilla, utilizing a minimum of two implants to support fixed or removable prosthetic devices in patients with partially or fully edentulous upper jaws, and may be suitable for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The procedure can be accomplished in a one-stage or two-stage surgical operation.

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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510k Summary

I. **SUBMITTER**

Noris Medical Ltd.
8 Hataasia St. 3688808
Nesher, Israel

Phone: 972-73-7964477

Contact Person: Biatrina Shidlovsky
Date Prepared: Feb 11, 2025

II. **DEVICE**

Name of Device: LONGY Implant and LONGY-N Implant
Common or Usual Name: Long Dental Implants System
Classification Name: Endosseous dental implant (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE

III. **PREDICATE DEVICE**

Neodent Implant System– GM Helix LG ® (K190958 Primary Predicate)
Noris Medical Ltd. - TUFF (K140440 Reference Device)
Neodent Implant System- Zygoma GM (K190718 Reference Device)
Noris Medical Ltd. - Zygomatic Implants (K151909 Reference Device)
Noris Medical Ltd. - MBI Dental Implant System (K153043 Reference Device)

IV. **DEVICE DESCRIPTION**

The subject dental implant devices are single use devices, provided sterile by Gamma Radiation, made of Titanium alloy Ti-6Al-4V ELI (ASTM F136). The LONGY Implants and LONGY-N Implants bare internal hex connection, diameters of 3.75 and 4.0mm and lengths of 18, 20, 22 and 25 mm. The Noris LONGY and LONGY-N implants are indicated for splinted restorations in the maxilla, utilizing a minimum of two implants to support fixed or removable prosthetic devices in patients with partially or fully edentulous upper jaws, and may be suitable for immediate loading when good primary stability is achieved.
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.
LONGY and LONGY-N dental implants are compatible with FDA cleared Noris Medical Ltd. Internal Hex platform abutments and superstructures only intended for multiple-unit loading, provided that they do not exceed an angulation of 30° (≤30̊).

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V. INDICATION FOR USE

The Noris LONGY and LONGY-N implants are indicated for splinted restorations in the maxilla, utilizing a minimum of two implants to support fixed or removable prosthetic devices in patients with partially or fully edentulous upper jaws, and may be suitable for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The procedure can be accomplished in a one-stage or two-stage surgical operation.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Device	SUBJECT DEVICE	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE	REFERENCE PREDICATE
	LONGY Implant	**LONGY-N Implant**	**GM Helix LG (K190958)**	**Tuff (K140440)**	**Zygoma GM (K190718)**
	Noris Medical Ltd.	**Noris Medical Ltd.**	**Neodent Implant System**	**Noris Medical Ltd.**	**Neodent Implant System**
Design Description	Threaded root-form implant to be used with matching abutments.	Threaded root-form implant with 2 flat surfaces to be used with matching abutments.	Threaded root-form implant with internal GM Morse taper connection with internal hex.	Threaded root-form implant to be used with matching abutments.	Threaded root-form implant to be used with matching abutments, made of Titanium grade 4. With 2 flat surfaces.
Indication for Use	The Noris LONGY and LONGY-N implants are indicated for splinted restorations in the maxilla, utilizing a minimum of two implants to support fixed or removable prosthetic devices in patients with partially or fully edentulous upper jaws, and may be suitable for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The procedure can be accomplished in a one-stage or two-stage surgical operation.	The Noris LONGY and LONGY-N implants are indicated for splinted restorations in the maxilla, utilizing a minimum of two implants to support fixed or removable prosthetic devices in patients with partially or fully edentulous upper jaws, and may be suitable for immediate loading when good primary stability is achieved. The procedure can be accomplished in a one-stage or two-stage surgical operation.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single- stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	Noris Medical Ltd 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.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading
Type	Bone level Implant	Bone level Implant	Bone level Implant	Bone level Implant	Bone level Implant

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Device	SUBJECT DEVICE	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE	REFERENCE PREDICATE
	LONGY Implant	**LONGY-N Implant**	**GM Helix LG (K190958)**	**Tuff (K140440)**	**Zygoma GM (K190718)**
	Noris Medical Ltd.	**Noris Medical Ltd.**	**Neodent Implant System**	**Noris Medical Ltd.**	**Neodent Implant System**
Implant Diameter [mm]	Ø 3.75 Ø 4.0	Ø 3.75 Ø 4.0	Ø 3.75 Ø 4.0	Ø 3.3 Ø 3.75 Ø 4.2 Ø 5 Ø 6	Ø 4.0
Length [mm]	18, 20, 22, 25	18, 20, 22, 25	20, 22.5, 25	8, 10, 11.5, 13, 16	30, 35, 37.5, 40, 42.5, 47.5, 50, 52.5, 55
Material	Titanium alloy Grade 23 Ti-6Al-4V ELI	Titanium alloy Grade 23 Ti-6Al-4V ELI	Commercially Pure Titanium (ASTM F67)	Titanium alloy Grade 23 Ti-6Al-4V ELI	Commercially Pure Titanium (ASTM F67) Grade 4
Surface Treatment	RBM (Resorbable Blasting Media)	RBM (Resorbable Blasting Media)	Sand blasted, acid etched NeoPoros surface.	RBM (Resorbable Blasting Media)	Sand blasted, acid etched NeoPoros surface.
Sterilization	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization
Single Use	Yes	Yes	Yes	Yes	Yes

VII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject devices and the primary predicate device have equivalent intended use and Indications for Use statements. Both indicated for splinted restorations utilizing a minimum of two implants to support fixed or removable prosthetic in the maxilla and may be loaded immediately when good primary stability is achieved.
The subject devices and the primary predicate devices present similar designs and have the same range of diameters and lengths. The subject devices have additional shorter non-worst-case devices. The subject device LONGY-N have a design modification identical to reference device K151909.
The subject devices and the primary predicate devices also share the same Gamma Irradiation sterilization method.
The subject devices and the primary predicate device have shown equivalent performance strength.
The subject devices and the reference device K140440 share the same material and surface treatment.
The subject devices have the same implant-to-abutment interface design as the reference device K140440.

VIII. PERFORMANCE DATA

Fatigue tests per ISO 14801 were performed to determine the fatigue strength for LONGY Implant and LONGY-N implants, according to FDA Guidance.

The LONGY and LONGY-N implants underwent comprehensive non-clinical testing to demonstrate substantial equivalence to the predicate devices in terms of safety and effectiveness. These evaluations included biocompatibility assessments, sterilization validation, shelf-life testing, mechanical testing, and additional process verifications as detailed below.

Non-clinical worst-case biocompatibility testing for the subject implants was leveraged based on the identical material, manufacturing processes, and surface treatments used in previously cleared devices under K151909. The tests included cytotoxicity (ISO 10993-5), sensitization and irritation (ISO 10993-10), and systemic and subchronic toxicity (ISO 10993-11), which confirmed the biocompatibility of the materials for their intended use.

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.

Similarly, the RBM (Resorbable Blasting Media) surface treatment process for the subject implants was leveraged, as it is identical to the surface treatment validated for Noris Medical implants cleared under K153043. This ensures consistent adherence to specifications and supports the reliability of the implants’ surface properties.

Furthermore, the sterilization process for the subject implants was leveraged, as it employs the same gamma irradiation method validated in accordance with ISO 11137-1 and ISO 11137-2, achieving a Sterility Assurance Level (SAL) of 10^-6. This method has been successfully validated for previously cleared devices under K140440, demonstrating compliance with sterilization requirements.

Based on the equivalence of material, design, and manufacturing processes with previously cleared devices, ensure that the subject implants meet all relevant safety and performance standards. The results of all tests confirmed that the LONGY and LONGY-N implants meet performance and safety requirements for their intended use and demonstrate substantial equivalence to the predicate devices.

I. CONCLUSION

Noris Medical's comparative analysis clearly demonstrates that any differences between our subject devices and predicate devices do not compromise safety or effectiveness. Modifications or improvements made to the design aim to enhance performance and patient outcomes without deviating from the fundamental characteristics of predicate devices.