October 11, 2024

JDentalCare Srl
% Pantaleoni Maurizio
Consultant
Maurizio Pantaleoni
Via Borgo Santa Cristina 12
Imoa, 40026
ITALY

Re: K240143
Trade/Device Name: JDZygoma dental implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 16, 2024
Received: September 16, 2024

Dear Pantaleoni Maurizio:

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,

Sherrill Lathrop Blitzer

for Andrew 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.

Submission Number *(if known)*

K240143

Device Name

JDZygoma dental implants

Indications for Use *(Describe)*

JDZygoma Dental implant is a JDentalCare implant system.
JDZygoma 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 maxilla, in order to restore patient esthetics and chewing function.
The JDZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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.

510(k) Summary

JDZYGOMA DENTAL IMPLANTS

This 510(k) Summary is being submitted per **21 CFR 807.92.**

1. General Information

Submitter:

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Summary Prepared Date: October 11, 2024

2. Names

Device Name:	***JDZYGOMA DENTAL IMPLANTS***
Classification Name:	Implant, Endosseous, Root-form
Product Code:	DZE
Secondary Product Code:	NHA
Regulation number:	872.3640
CLASS	II

3. Predicate and Reference Devices

The ***JDZYGOMA DENTAL IMPLANTS,*** is substantially equivalent to the following predicate device legally marketed in US:

Applicant	*Device name*	*510(k) Number*
Noris Medical	Noris Medical Dental Implants System (Primary Predicate device)	K151909

Reference devices that have been used for comparison of technological features are the following:

Applicant	*Device name*	*510(k) Number*
Noris Medical	Noris Medical Dental Implants System	K210356
Nobel Biocare AB	NobelZygoma 45°	K152093
Nobel Biocare AB	Zygoma Angled Abutments	K052885
Southern Implants (Pty) Ltd	Zygomatic Implant System (ZYGAN)	K173343
J DENTAL CARE S.r.l.	JDIcon	K182081

4. Device Description

JDZygoma dental implants are implantable devices produced in commercially pure titanium, intended to be integrated in the Zygomatic bone to support prosthetic devices, such as artificial teeth, in order to restore chewing function.

The JDZygoma implant bodies are single use, gamma sterilized devices that shall be used by qualified medical personnel. The abutments are supplied non sterile and must be sterilized prior to use.

The JDZYGOMA DENTAL IMPLANTS includes 2 lines of devices with different body diameters of implants (3.9 mm and 4.3 mm) with different implant lengths:

- Diameter(mm) 3.9 – Lengths (mm): 30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5 / 55 / 57.5
- Diameter(mm) 4.3 – Lengths (mm): 30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5 / 55 / 57.5

The surfaces JDZYGOMA DENTAL IMPLANTS, both 3.9 mm and 4.3 mm of diameter, is machined in the distal part of the fixture while the apical part, the threaded part, is characterized by a surface that is a SLA surface obtained through a sandblasting process followed by acid etching.
Machined surface has been analyzed form a morphological point of view using scanning electron microscope (SEM) with different level of magnification (100x, 500x, 1000x and 2500x) and also performing a 3D analysis, that allow to define roughness profile with an average height of selected area (Sa) equal to 0.64 µm, with a Root mean square gradient (Sdq) of 1.06 and a developed interfacial area ratio (Sdr) of 47.64%.

The abutments are made of titanium grade 5 and have the following angulations:

- 45° 52.5° and 60°

The connection implant / abutment is done through an internal hexagon.

The conical abutments surface is completely treated with anodic oxidation resulting in perception of yellow color.

The anodization process is performed by immersing the abutments in the anodization solution and by providing an electrical voltage for a time necessary to activate the process with the material (titanium grade 5) and then performing washing process and drying the devices.
The result of this process has been evaluated from a morphological point of view using scanning electron microscope (SEM), measuring the roughness parameters and performing qualitative analysis of the chemical composition of the abutments surface with X-Ray detector considering and comparing both a non anodized abutments and the same anodized abutments in their finished forms.
These evaluations show a relatively uniform surface with characteristic textures of typical machined titanium, clean and free from significant residues or contaminants, with a morphology of the surface before and after anodization that doesn't show appreciable differences also for roughness and X-ray analysis identify a presence of only of Ti, Al, V, O, as expected.

5. Indications for Use

JDZygoma Dental implant is a JDentalCare implant system.
JDZygoma 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 maxilla, in order to restore patient esthetics and chewing function.
The JDZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

6. Comparison of the technological characteristics with the predicate and reference devices

	Subject device JDENTALCARE	**Primary Predicate device Noris Medical**	**Reference device Nobel Biocare AB**
	Implant System JDZygoma	**Noris Medical Zygomatic Implants System (K151909)**	**Nobel Zygoma 45° (K152093)**
Regulation Number:	872.3640 - Endosseous dental implant	872.3640 - Endosseous dental implant.	872.3640 - Endosseous dental implant.
Classification	II	II	II
Product Code	DZE (implant) NHA (Abutments)	DZE (implant) NHA (Abutments)	DZE (implant)
Intended Use	JDZygoma dental implant is a JDentalCare implant system. JDZygoma 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**, in order to **restore** patient esthetics and **chewing function**. The JDZygoma Implants are	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**	Nobel Biocare's Zygoma implants are endosseous dental implants 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 patient esthetics and chewing function. The Zygoma Implants **may be put into immediate function**

	appropriate **for immediate loading when good primary stability is achieved and with appropriate occlusal loading**.	**upper jaw** arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.	**provided that stability requirements detailed in the directions for use are satisfied**.
Indication	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load
Placement method	Extra maxillary	Extra maxillary	Inside or outside the maxillary sinus

Table 1 - Regulatory Comparison Table

	Subject device JDENTALCARE		**Primary Predicate device Noris Medical**	**Reference device Nobel Biocare AB**
	Implant System JDZygoma Diameter 3.9	**Implant System JDZygoma** Diameter 4.3	**Noris Medical Zygomatic Implants System (K151909)**	**Nobel Zygoma 45° (K152093)**
Design & Mechanical features				
Materials	Titanium grade 4	Titanium grade 4	Titanium alloy (Grade 5)	Titanium grade 4
Shape	Two pieces Cylindrical screw straight 0°	Two pieces Cylindrical screw straight 0°	Two pieces Cylindrical screw straight 0°	Two pieces Cylindrical screw preangled 45°
Connections	Internal Hexagon Conical connection Platform Diam: 3.4 mm Int. Hex Diam: 2,425mm	Internal Hexagon Conical connection Platform Diam: 3.4 mm Int. Hex Diam: 2,425mm	Internal Hexagon Conical connection Platform Diam: 3,75 mm Int. Hex Diam: 2,42mm	External Hexagon
Diameters (mm)	4.35 max diameter (at platform level) 3.9 body 3.9 apex	4.5 max diameter (at platform level) 4.3 body 4.3 apex	4.2 max diameter 3.75mm platform 4.2 body 3.5 apex	4.5 platform- 4.0 body 3.9 apex
Lengths	30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5/ 55 / 57.5	30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5/ 55/ 57.5	Diameter 4.2 30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5/ 55/ 57.5	Diameter 4.0 30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5
Abutment	45°; 52.5°;60°	45°; 52.5°; 60°	17°, 30°, 45° (Extended at 52° and 60° with K210356)	45°, 62° (62° with the use of K052885)
Design of the Thread				
Thread Length (starts at apex and extends coronally	16 mm	18 mm	13 mm	18 mm
Thread design	Double lead	Double lead	Double lead	Single lead
Thread Pitch	1.295mm	0.645mm	1.295mm	0.600mm
Thread Depth	0.400mm (mean)	0.330mm (mean)	0.500mm (mean)	0.320mm
Thread Width	0.200mm	0.100mm	0.200mm	0.100mm
Design of the surfaces				

	Subject device JDENTALCARE		**Primary Predicate device Noris Medical**	**Reference device Nobel Biocare AB**
	Implant System JDZygoma Diameter 3.9	**Implant System JDZygoma** Diameter 4.3	**Noris Medical Zygomatic Implants System (K151909)**	**Nobel Zygoma 45° (K152093)**
Apex parts	Sandblasting followed by acid etching	Sandblasting followed by acid etching	RBM (Resorbable Blast Media)	TiUnite
Treated surface height	18 mm	18 mm	16 mm	TiUnite
Crestal part of the implant	Machined	Machined	Machined	TiUnite
Design – Dimensions (mm)				
Packaging				
kind of package	plastic vial + blister	plastic vial + blister	plastic vial + blister	plastic vial + blister
Sterile	Yes Gamma Radiation	Yes Gamma Radiation	Yes Gamma Radiation	Yes Gamma Radiation

Table 2 - Comparison Table for Endosseous Implants fixtures

	Subject device JDENTALCARE	**Primary Predicate device Noris Medical**	**Reference device**
Features	**Implant System JDZygoma**	**Noris Medical Zygomatic Implants System (K151909 + K210356)**	**Zygoma Angled Abutments (K052885)**
Design			
Images of angulated abutments			
Angles	45°, 52.5°, 60°	17°, 30°, 45°, 52° (*), 60° (*)	0°, 17° (work angle from 45° to 62° with the implant)
Abutments Height	4.5 and 5.0mm	2, 5 mm	2, 3, 5 mm
Materials			
Materials	Titanium grade 5	Titanium grade 5	Titanium grade 5
Packaging			
Sterility	Non sterile	Non Sterile	Non Sterile

Table 3 - Comparison Table for Abutments

The fixtures included in the JDentalCare implant system JDZygoma are considered substantially equivalent to the predicate and reference devices due to the following:

1) the difference in material respect to the primary predicate device (titanium grade 4 vs 5) doesn't affect the safety and effectiveness of the device, and material is the same material of the reference device.
2) are two-pieces implants with a cylindrical shape, straight 0° platform exactly as the primary predicate device Noris Medical Zygomatic Implants System (K151909).

3) has a conical connection with internal hexagon, exactly as the primary predicate device with an internal Diameter of the hexagon very similar to the one of the primary predicate device.
4) diameter, length and work angles are within the range of the predicate devices and/or of the reference device.
5) the thread of JDentalCare implant system JDZygoma can be considered substantially equivalent to the thread of the predicate and reference devices.
6) the surface treatment used in JDentalCare implant system JDZygoma doesn't introduce any new issues related to safety and effectiveness of the devices

Finally, where differences are present these are supported also by the availability of the reference devices and by the results of:

- The comparative mechanical fatigue test executed on the worst cases configuration in comparison with the predicate and reference device, that confirms that fatigue performances of the subject device are comparable to or better than both predicate and reference Devices.
- Real World Evidence

7. Performance Data (non clinical)

A program of design verification and validation testing was performed that includes the following:

- Biocompatibility was conducted according to ISO 10993-1:2018 and ISO 10993-5
- Verification of Washing Process testing was conducted to demonstrate that no residuals substances were present on implant or abutment surface
- Packaging shelf life accelerated aging testing was conducted according to ISO 11607-1
- Comparative mechanical fatigue testing was performed according to a method modified from ISO 14801, on worst-case test articles from the subject, predicate, and reference devices, to best represent the extra-maxillary surgical method
- Gamma Ray Sterilization Validation in accordance with ISO 11137-1:2006 and ISO 11137-2: 2013
- Endotoxin tests is performed on all the batches of JDZygoma implants with the highest dental implant surface, to demonstrate that the pyrogen limit specifications through LAL test according to the United States Pharmacopeial Convention is always respected

Results of the evaluations demonstrate that the subject device demonstrated substantially equivalence performance as per its indication for use.

8. Clinical data

To support the use of the JDZygoma dental system, including different proposed angulations, implant diameter, and length for use with the extra-maxillary surgical method, real world evidence was provided in the form of two retrospective studies, respectively relevant for JDZygoma lines diameter 3.9mm and 4.3mm with follow-up after placement of 1 year and 3 years.

143 JDZygoma dental implants of the two diameters and different lengths were placed in male and female adult population for a total of 66 patients. Distribution of the implants by the site, position, length, and diameter varied. Implant/abutment success, prosthetic survival, general postoperative complications have been evaluated as lso Modified Plaque Index (mPLI), modified Bleeding Index (mBI), Mucosal Seal Efficacy Evaluation (MSEE) and Zygomatic Implants Classification Level (ZICL), as secondary outcomes.
Outcome measures were evaluated, for the 3.9mm JDZygoma implants at 1 year post-surgery and for 4.3mm implants at 3 years post-surgery.

Based on results of these studies, the survival rates of the 3.9mm and 4.3mm implants which met the criteria for successful implant osseointegration, were 100% for both the studies and no differences were registered among clinical indices related to the different abutments inclinations.

9. Conclusions

The JDZYGOMA DENTAL IMPLANTS was evaluated for substantial equivalence using standards, comparative testing and real world evidences.
The totality of information combined between the real world evidence and bench testing was provided to support the performance of the implant-abutment configuration up to 60° with lengths of 55mm and 57.5mm for the diameter of 3.9mm for the demonstration of substantial equivalence.