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

September 25, 2025

Re: K251148
Trade/Device Name: JDEvolution Plus L and JDEvolution Plus LE
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: March 31, 2025
Received: August 26, 2025

Dear Maurizio Pantaleoni:

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)*
K251148

Device Name
JDEvolution Plus L and JDEvolution Plus LE

Indications for Use *(Describe)*
JDEvolution Plus L and JDEvolution Plus LE implant system is intended for surgical placement in the upper jaw.
JDEvolution Plus L and JDEvolution Plus LE implant system provides a means for prosthetic attachment in partially or fully edentulous spans with multiple teeth utilizing delayed, or immediate loading, or as a terminal or intermediary abutment for fixed ore removable bridgework or to retain overdentures. JDEvolution Plus L and JDEvolution Plus LE is intended for immediate function multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

JDEvolution Plus L and JDEvolution Plus LE implants with lengths of 18, 20, 22, 24, 26 mm are only indicated for multiple unit restorations in splinted applications with at least two implants when placed in the maxilla.

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

JDEvolution Plus L and JDEvolution Plus LE
K251148

This 510(k) Summary is being submitted as required by **21 CFR 807.92.**

1. General Information

Submitter:

J DENTAL CARE S.r.l. is located at:
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Consultant/ Contact:

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Summary Prepared Date:

September 25, 2025

2. Names

Device Name:	***JDEvolution Plus L and JDEvolution Plus LE***
Classification Name:	Endosseous dental implant
Product Code:	DZE
Secondary Product Code:	N.A.
Regulation number:	872.3640
CLASS	II

3. Predicate Devices

The JDEvolution Plus L and LE, are substantially equivalent to the following predicate device legally marketed in US:

Applicant	*Device name*	*510(k) Number*	*Product code*
Nobel Biocare AB	NobelSpeedy® Groovy	K160119	DZE

This predicate device has not been subject to a design-related recall.

Reference device that has been considered is the following:

Applicant	*Device name*	*510(k) Number*	*Product code*
J DENTAL CARE S.r.l.	JDEvolution	K143142	DZE, NHA
J DENTAL CARE S.r.l.	JDIcon	K182081	DZE, NHA
J DENTAL CARE S.r.l.	JDentalCare Dental Implant System: JDEvolution plus; JDEvolution S; JDIcon	K233896	DZE, NHA
Nobel Biocare AB	NobelSpeedy Implants	K050406	DZE

This reference device has not been subject to a design-related recall.

4. Device Description

General

JDEvolution Plus L and LE, are tissue level implantable devices produced in commercially pure titanium, intended for surgical placement in the upper jaw to support prosthetic devices, such as artificial teeth, in order to restore chewing function.

JDEvolution Plus L and LE are endosseous dental implants intended for surgical placement in the upper jaw.
JDEvolution Plus L and LE implants includes dental implant fixtures only.
JDEvolution Plus L and LE provide a means for prosthetic attachment partially or fully edentulous spans with multiple teeth utilizing delayed or immediate loading when good primary stability is achieved in order to restore patient chewing function.
The subject implant bodies are compatible with abutments cleared in K143142 and K233896

Knowledgeable clinicians are in charge for the following of a delayed instead immediate loading, evaluating the stability of the implant sites after the surgical operation.

The device insertion occurs at the end of the surgical procedure which consists in an osteotomy of the upper jaw.

JDEvolution Plus L and LE implants are single use devices, supplied sterile and that cannot be re-cleaned or re-sterilised.

Product Description

JDEvolution Plus L and LE *Implant System* is a two-piece implant made of commercially pure titanium.
The body of the implant fixture (Endosseous Dental Implant) is surgically placed in the upper or lower jaw, while the Abutment (several type for several clinical application) is screwed into the fixture to support the prosthesis.
The connection is done through an internal hexagon: abutments and other accessories are exclusively designed for ***JDEvolution Plus L and LE*** *Implant System*.
Endosseous dental implant and abutment will represent the support, for the dentist, for building the artificial replacement tooth.
The artificial replacement tooth component is not part of this submission.

The main features of JDEvolution Plus L and LE Implant System are summarized in the table below:

	JDEvolution Plus
Materials	Titanium grade 4 (diameter 4.0)
Design	
General	
General Features	Endosseous implant with connection with internal hexagon
Shape:	
Collar	Machined gingival collar of 1,5mm length for all the lengths
Body	Double thread with 0.6 mm lead: straight cylindrical of 4,0 mm diameter for a total length (including collar) of 20 / 22 / 24 / 26mm. Tapered apex with bone cutting flutes. Double thread with 1.2 mm lead: tapered body of 4,0 mm for a total length (including collar) of 18 / 20 / 22 / 24 / 26mm
Thread	Double thread with 0.6 mm or 1.2 mm lead
Abutment	To be connected with the Conical abutment cleared under K143142, K233896 Ti gr.5: Straight– angled 15° - angled 17° - angled 25°- angled 30°
Surface:	
Collar	Machined, without any surface treatment
Body	Treated through sandblasting followed by acid etching (SLA) for the full length of the endosseous portion for all variants (the surface treatment is the same of the JDentalCare Implant System JDIcon cleared under K 182081)
Thread:	
Body	Double thread outline: trapezoidal Thread lead: 0.6 mm (for tapered body version) Thread lead: 1.2 mm (for straight cylindrical body version)
Self-Threading Capacity	Self-threading capacity in both direction
Dimensions:	
Mean Diameter	4.0 mm
Total Length	18mm (only for JD Evolution Plus LE Implant), 20mm, 22mm, 24mm and 26mm
Implanted Length	16.5mm (only for JD Evolution Plus LE Implant), 18.5mm, 20.5mm, 22.5mm and 24.5mm
Connection:	
Shape	Internal hexagonal connection (Hexagon dimension of 2.425 mm)
Packaging:	

	JDEvolution Plus
Type of package	Blister with internal vial and protective cap for implants External carton box as commercial packaging
Blister material:	Tyvek Polyester PET MO65
Vial material:	Polystyrene Empera 116 vial closed with Eralyte PET cap

5. Indications for Use

JDEvolution Plus L and JDEvolution Plus LE implant system is intended for surgical placement in the upper jaw.
JDEvolution Plus L and JDEvolution Plus LE implant system provides a means for prosthetic attachment in partially or fully edentulous spans with multiple teeth utilizing delayed, or immediate loading, or as a terminal or intermediary abutment for fixed ore removable bridgework or to retain overdentures. JDEvolution Plus L and JDEvolution Plus LE is intended for immediate function multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

JDEvolution Plus L and JDEvolution Plus LE implants with lengths of 18, 20, 22, 24, 26 mm are only indicated for multiple unit restorations in splinted applications with at least two implants when placed in the maxilla.

6. Comparison of the technological characteristics with the predicate device

	JDENTALCARE Implant System	**Predicate device**
	JDEvolution Plus L and LE	**NobelSpeedy® Groovy (K160119)**
Regulation Number:	872.3640 - Endosseous dental implant.	872.3640 - Endosseous dental implant.
Classification	II	II
Product Code	DZE (implant)	DZE (implant)
Intended Use	JDEvolution Plus L and JDEvolution Plus LE implant system is intended for surgical placement in the upper jaw. JDEvolution Plus L and JDEvolution Plus LE implant system provides a means for prosthetic attachment in partially or fully edentulous spans with multiple teeth utilizing delayed, or immediate loading, or as a terminal or intermediary abutment for fixed ore removable bridgework or to retain overdentures. JDEvolution Plus L and JDEvolution Plus LE is intended for immediate function multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. JDEvolution Plus L and JDEvolution Plus LE implants with lengths of 18, 20, 22, 24, 26 mm are only indicated for multiple unit restorations in splinted applications with at least two implants when placed in the maxilla.	NobelSpeedy® Groovy implants are endosseous dental implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacement to restore patient aesthetics and chewing function. NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2- stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi-cortical anchorage in cases of reduced bone density NobelSpeedy ® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
Indication	Immediate or delayed load with dual or single stage surgery.	Immediate, early or delayed load with dual or single stage surgery Implants allow also for bi-cortical anchorage in cases of reduced bone density NobelSpeedy

Regulatory and Clinical Comparison Table

	JDENTALCARE Implant System	**Predicate device**
	JDEvolution Plus L and LE	**NobelSpeedy® Groovy (K160119)**
Design - Mechanical features		
Implant Body Design	Tissue level Straight cylindrical Tapered apex with bone cutting flutes. or, Tapered body from the apex to the neck of the implant	Bone level Tapered apex with bone cutting flutes
Thread Design	Double thread with 0.6 mm or 1.2 mm lead	Single lead thread with groove
Neck	Machined implant collar of 1.5mm	Collar with crestal grooves
Connection Type	Internal Hexagon	External Hexagonal
Dimensions		
Total length	18 (only for JD Evolution Plus LE Implant), 20, 22, 24, 26 mm	20, 22, 25 mm
Implanted length	16.5 (only for JD Evolution Plus LE Implant), 18.5, 20.5, 22.5, 24.5 mm	20, 22, 25 mm
Implant Width	4.0 mm	4.0 mm
Materials		
Device Material	Titanium	Titanium
Surface treatments		
Surface	Sandblasting followed by acid etching (SLA)	TiUnite
Packaging		
kind of package	plastic vial + blister	vial + blister
Sterile	Yes Gamma Radiation	Yes Gamma Radiation

Technical and Biological comparison table

7. Performance Data (non clinical)

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

- Biocompatibility
  A biocompatibility evaluation per ISO 10993-1 was performed for the subject devices. Biocompatibilty testing was leveraged from K182081 as there are no changes in the materials or manufacturing process from that submission

- SEM and EDS testing has been leveraged from K182081 as the manufacturing process for those devices is identical to the subject devices.

- Bacterial endotoxin testing (LAL) is conducted according to USP <161> and <85>.

- Verification of Washing Process
  Washing process is done on all JDENTALCARE products and it has been verified in order to demonstrate that on the subject device are not present chemical agents due to the manufacturing process. The results of the decontamination were verified through the following tests:
  - UV-Vis spectrophotometric absorbance
  - Reducing substances
  - Spectrophotometric analysis to determine the presence of substances derived by manufacturing and washing process

- Packaging shelf-life accelerated aging tests
  The shelf life of the JDEvolution Plus L and LE is 5 years. The sterilization method for implant fixtures is the same already validated for the predicate device JDICon (K182081), the materials of the implants and the packaging are the same of the predicate device JDICon (K182081).

- Gamma Ray Sterilization Validation
  The JDEvolution Plus L and LE are sterilized with a Gamma-ray sterilization method. The sterilization validation for gamma-ray irradiation was conducted according to ANSI/AAMI/ISO ISO 11137

- Mechanical performance tests
  Mechanical test were performed on JDEvolution Plus L & LE implant in comparison with the predicate device, following FDA guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and ISO 14801: 2016 confirming that the mechanical performance of JDEvolution Plus L& LE implant in conjunction with the straight or angled abutments can be considered substantially equivalent with the predicate device
  Furthermore a torsional test was carried out to measure the torsional yield strength, maximum torque and the breaking angle in compliance with ISO/TS 13498:2011 of subject device in comparison of the predicate device confirming that subject device performs equivalently to the predicate device

- MRI Environment
  The MR language was leveraged by K233896. 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.

Results of the evaluations demonstrate that the subject device met the safety and performance requirements as per its indication for use.

8. Clinical data

N/A

9. Conclusions

The JDEvolution Plus L and LE implants were evaluated for substantial equivalence using comparative bench tests in comparison with the predicate device. Based on technological characteristics and non-clinical test data, the JDEvolution Plus L and LE has been shown to be substantially equivalent to the predicate device.