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

August 16, 2024

Re: K233896
Trade/Device Name: JDentalCare Dental Implant System: JDEvolution; JDEvolution plus; JDIcon; JDIcon plus
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 18, 2024
Received: July 22, 2024

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.

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)*
K233896

Device Name
JDentalCare Dental Implant System: JDEvolution; JDEvolution plus; JDIcon; JDIcon plus

Indications for Use *(Describe)*
JDentalCare Dental Implant System, family names JDEvolution, JDEvolution Plus, JDIcon, JDIcon Plus, is intended to replace missing masticatory functional units (teeth) within the maxilla or mandible.
JDentalCare Dental Implant System is comprised of dental implant fixtures and prosthetic devices. It provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare Dental Implant System is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
Implants 20 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
JDentalCare implant system JDIcon 2.75mm D Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors for single stage or two stage procedures. It is for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations

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

JDentalCare® Dental Implant System

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:
Via Dino Campana, 2
MODENA
ITALY
Tel. +39 059 454255
Fax +39 059 450045

Consultant/ Contact:

Maurizio Pantaleoni
Via Borgo Santa Cristina 12
40026 Imola (BO)
Mobile: +39 348-4435155
Email: maurizio.pantaleoni@gmail.com

Summary Prepared Date: August 16, 2024

2. Names

Device Name:	***JDentalCare Dental Implant System: JDEvolution; JDEvolution plus; JDIcon; JDIcon plus***
Classification Name:	Implant, Endosseous, Root-form / Endosseous dental implant abutment
Product Code:	DZE
Secondary Product Code:	NHA
Regulation number:	872.3640
CLASS	II

3. Predicate Devices

The ***JDentalCare® Dental Implant System,*** is substantially equivalent to the following predicate device legally marketed in US:

Applicant	*Device name*	*510(k) Number*	*Product code*
J DENTAL CARE S.r.l.	JDentalCare® Implant System JDIcon®	K182081	DZE NHA

These predicate devices have not been subject to a design-related recall.

Reference devices that have been considered are the following:

Applicant	*Device name*	*510(k) Number*	*Product code*
J DENTAL CARE S.r.l.	JDentalCare® Implant System JDEvolution®	K143142	DZE NHA
Adin Dental Implants Systems Ltd.	TOUAREG CloseFit™ UNP 2.75mmD	K153111	DZE NHA
Nobel Biocare AB	TiUltra Implants and Xeal Abutments	K202344	DZE
Nobel Biocare AB	NobelSpeedy® Groovy	K160119	DZE
Nobel Biocare AB	Nobel Active	K142260	DZE NHA
Nobel Biocare AB	Nobel Biocare Healing Cap Multi-Unit Titanium	K171142	NHA
MIS Implants Technologies	MIS V3 Conical Connection Dental Implant System	K163349	DZE NHA

This reference devices have not been subject to a design-related recall.

4. Device Description

General

Dental implant surgery is a procedure that replaces tooth roots with metal, screwlike posts and replaces damaged or missing teeth with artificial teeth.

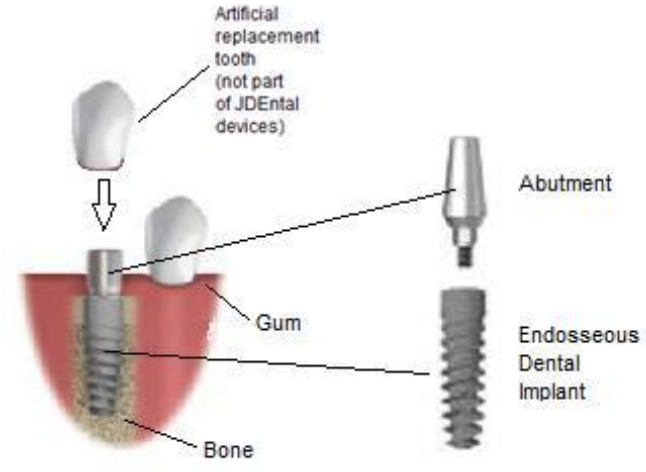
Dental implant surgery can offer an alternative to dentures or bridgework and can offer an option when a lack of natural teeth roots don't allow building denture or bridgework tooth replacements. How dental implant surgery is performed depends on the type of implant and the condition of the jawbone. Dental implant surgery may involve several procedures. The major benefit of implants is solid support for your new teeth — a process that requires the bone to heal tightly around the implant.

JDentalCare S.r.l. manufactures Dental Implant Systems made by Endosseous Dental Implants, Abutment and related accessories, in order to support dentist in performing Dental Implant Surgery.

In order to grant Dentists with a wide range of prosthesis solution, the ***JDentalCare® Dental Implant System*** are proposed with different trade name within families lines ***JDEvolution, JDEvolution® plus, JDIcon®, JDIcon® plus,*** characterized mainly by same mechanical and surface treatment solution and different measure of the hexagon in the connection system. All families have the internal hexagon connection.

Implants Description

JDentalCare® Dental 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: abutment and other accessories are exclusively designed for ***JDentalCare® Dental 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 the JDentalCare® Dental Implant System added in this submission at the previous devices already cleared with K143142 and K182081 are summarized in table below:

JDentalCare® Dental Implant System		
Design		
General:		
General Features	Two pieces dental implant system with internal hexagon connection	
Shape:		
Implant Body	Tapered screw	
Implant Neck	Cylindrical	
Implants Materials:	Diameter 3.5 – 3.7 – 3.9 –4.0 – 4.3 – 4.5 – 5.0 – 6.0	Titanium Grade 4
Abutment material:	All abutments	Titanium Grade 5
Surface:		
Implant	Implants JDEvolution Plus, JDIcon, JDIcon Plus are treated through sandblasting followed by acid etching (SLA)	
Neck	***JDEvolution plus –*** Available with: - fully treated collar or - 1.5 mm anodized collar both for model with 1.2 and 0.6 mm pitch - 2.5 mm anodized collar only for model with 1.2 mm pitch and 4.0 mm diameter ***JDEvolution:*** no new dental implants introduced, but only prosthetic components introduced in this submission ***JDIcon –*** Available with - fully treated collar or - 1.5 mm machined collar	

JDentalCare® Dental Implant System	
	JDIcon plus – Available with: - fully treated collar, both for model with 1.2 and 0.8 mm pitch or - 1.5 mm anodized collar only for double thread models
Abutment	Abutment surface can be: - Smooth/Machined (no treatment) - Anodized (Yellow, Green, Purple, Magenta) (Ref to section below about prosthetic components)
Thread:	
Body	Double thread Pitch can be different for the different models: ***JDEvolution plus*** - Pitch 1.2 mm for fully treated collar - Pitch 1.2 mm for 1.5 mm and 2.5 mm anodized collar - Pitch 0.6 mm for 1.5 mm anodized collar (only 4.0 diameter) ***JDEvolution:*** no new dental implants introduced, but only prosthetic components introduced in this submission ***JDIcon –*** Available with - Pitch 1.2 mm for fully treated collar or - Pitch 1.2 mm for 1.5 mm machined collar ***JDIcon plus –*** Available with: - Pitch 1.2 mm for 1.5 mm anodized collar - Pitch 1.2 mm for fully treated collar, - Pitch 0.8 mm (single thread) and fully treated collar (*Only for JDIcon plus 3.5 mm, 4.0 mm, 4.5 mm*)
Self-Threading Capacity	Self-threading capacity in both direction
Implant Dimensions (refer to tables below for more details)	
Diameter	From 3.5 to 6 mm
Length	From 8 to 20 mm
Neck diameter	From 3.7 to 6 mm
Connection:	
Shape	Internal hexagon (JDEvolution Plus, JDEvolution) Conical with internal hexagon (JDIcon and JDIcon Plus)
Packaging	
Type of package	Blister with internal vial for implants
Materials:	
Blister:	Tyvek CR27 / Polyester PETG
Vial:	Polystyrene EMPERA 116

The specific diameter / length implant body combinations for each implant proposed in this submission are listed below:

JDEvolution® PLUS // FULLY TREATED + SLA + Pitch 1.2mm	
Dia	**Length**
3.7	18
4.3	18
5.0	18

JDEvolution® PLUS // ANODIZED COLLAR (1.5mm) + SLA + Pitch 1.2mm						
Dia	**Length**					
3.7	8	10	11.5	13	15	18
4.3	8	10	11.5	13	15	18
5.0	8	10	11.5	13	15	18
6.0	8	10	11.5	13	15	/

JDEvolution® PLUS // ANODIZED COLLAR (2.5mm) + SLA + Pitch 1.2 mm					
Dia	**Length (mm)**				
4.0	11.5	13	15	18	20

JDEvolution® PLUS // ANODIZED COLLAR (1.5mm) + SLA + Pitch 0.6 mm						
Dia	**Length (mm)**					
4.0	8	10	11.5	13	15	18

JDIcon® // FULLY TREATED + Pitch 1.2 mm	
Dia.	**Length**
3.9	18

JDIcon® // MACHINED COLLAR + Pitch 1.2 mm	
Dia.	**Length**
3.9	18

JDIcon® PLUS // ANODIZED COLLAR (1.5 mm) + SLA + pitch 1.2 mm						
Dia.	**Length**					
3.7	8	10	11.5	13	15	18
4.3	8	10	11.5	13	15	18
5.0	8	10	11.5	13	/	/

JDIcon® PLUS // FULLY TREATED SLA + pitch 1.2 mm						
Dia.	**Length**					
3.7	8	10	11.5	13	15	18
4.3	8	10	11.5	13	15	18
5.0	8	10	11.5	13	/	/

JDIcon® PLUS // FULLY TREATED SLA + pitch 0.8 mm (*)				
Dia.	**Length**			
3.5 (*)	/	10	11.5	13
4.0	8.5	10	11.5	13
4.5	8.5	10	11.5	13

JDIcon Plus implants with 3.5 mm diameter are intended to be used only with straight abutments.

Abutments Description

The abutments included in the ***JDentalCare® Dental Implant System*** can be divided into the following types:

	JDEvolution Plus ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
HEALING ABUTMENT: used in the delayed loading technique to close the implant connection for non-submerged healing. It helps the gum to heal properly. The abutment is screwed into the implant. Available with or without anodization. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**5**	**4,6,9**	**/**	**/**
TEMPORARY ABUTMENT: (engaging / non engaging): used for the fabrication of temporary restorations. Engaging and non-engaging variants are used for single- and multiple-unit restorations, respectively. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**3.1**	**2**	**10**	**/**

	JDEvolution Plus ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
STRAIGHT ABUTMENTS: indicated for cemented prosthesis of single and multiple units. Collar height can be of 0,5 mm, 1,5 mm, 2 mm, 3 mm or 4 mm depending on the height of soft tissues. Collar height of 0,5 mm available also in both engaging/non engaging version for single- and multiple-unit restorations, respectively. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**4** **5**	**0.5** **2 - 4**	**7** **7**	**/**
GP ABUTMENTS (engaging / non engaging): indicated for restorations of single and multiple implants. They can be modified with a drill and they can be used as definitive abutment.	**4** **5** **4.5** **4.5**	**1** **1.5** **1.5** **1.5**	**10** **10** **10** **10**	**0°** **0°** **15°** **25°**
CONICAL ABUTMENTS: indicated for screwed-in prosthesis. Conical abutments, available in both straight and angulated models are intended to be used only for multi-unit restorations. The "tissue lovers" models are characterized by a concave abutment profile.	**4.8**	**1 -7 – 9** **1.5 -3- 4- 5** **2.5 – 3.5** **2.5-3.5-5**	**2.2** **2.2** **2.2** **2.2**	**0°** **0°** **17°** **30°**

	JDEvolution D3.25 ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
CONICAL ABUTMENTS: indicated for screwed-in prosthesis. Conical abutments, available in both straight and angulated models are intended to be used only for multi-unit restorations. The "tissue lovers" models are characterized by a concave abutment profile.	**4.8**	**3** **3.5** **3.5** **1.5 - 3** **2.5 – 3.5** **2.5-3.5**	**2.2** **2.2** **2.2** **2.2** **2.2** **2.2**	**0°** **17°** **30°** **0°** **17°** **30°**

	JDICON ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
HEALING ABUTMENT: used in the delayed loading technique to close the implant connection for non-submerged healing. It helps the gum to heal properly. The abutment is screwed into the implant. Available with or without anodization. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**5**	**9**	**/**	**/**
TEMPORARY ABUTMENT: (engaging / non engaging): used for the fabrication of temporary restorations. Engaging and non-engaging variants are used for single- and multiple-unit restorations, respectively. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**4.4**	**1.3**	**10**	**/**
ANATOMIC ABUTMENTS: indicated for cemented prosthesis of single and multiple units. The anatomic abutment has an anatomical festoon preparation of the cervical margin that ensure lesser need of abutment preparation.	**5.5**	**1.5 – 3** **1.5 – 3**	**7.5** **7.5**	**15°** **25°**
CONICAL ABUTMENTS: indicated for screwed-in prosthesis. Conical abutments, available in both straight and angulated are intended to be used only for multi-unit restorations. The "tissue lovers" models are characterized by a concave abutment profile.	**4.8**	**2.5 – 3.5** **2.5 – 3.5**	**2.2** **2.2**	**17°** **30°**
STRAIGHT ABUTMENTS: indicated for cemented prosthesis of single and multiple units. Collar height can be of 0,5 mm, 1,5 mm, 2 mm, 3 mm or 4 mm depending on the height of soft tissues. Collar height of 0,5 mm available also in both engaging/non engaging version for single- and multiple-unit restorations, respectively. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**3.5**	**1-2**	**7**	**/**

	JDICON D2.75 ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
GP ABUTMENTS (engaging / non engaging): indicated for restorations of single and multiple implants. They can be modified with a drill and they can be used as definitive abutment.	**4**	**1.5**	**10**	**15°**

	JDICON D2.75 ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
CONICAL ABUTMENTS: indicated for screwed-in prosthesis. Conical abutments, available in both straight and angulated are intended to be used only for multi-unit restorations. The "tissue lovers" models are characterized by a concave abutment profile.	**4.8**	**1.5** **2.5**	**2.2** **2.2**	**0°** **17°**

	JDICON Plus ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
HEALING ABUTMENT: used in the delayed loading technique to close the implant connection for non-submerged healing. It helps the gum to heal properly. The abutment is screwed into the implant. Available with or without anodization. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**4** **5** **6** **7.5**	**3-5-7** **3-5-7** **3-5-7** **3-5**	**/**	**/**
TEMPORARY ABUTMENT: (engaging / non engaging): used for the fabrication of temporary restorations. Engaging and non-engaging variants are used for single- and multiple-unit restorations, respectively. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**3.7**	**2**	**10**	**/**
STRAIGHT ABUTMENTS: indicated for cemented prosthesis of single and multiple units. Collar height can be of 0,5 mm, 1,5 mm, 2 mm, 3 mm or 4 mm depending on the height of soft tissues. Collar height of 0,5 mm available also in both engaging/non engaging version for single- and multiple-unit restorations, respectively. The "tissue lovers" models are characterized by a concave abutment profile and a yellow anodization.	**4.5** **5** **5.5** **6.0**	**2 – 4** **2 - 4** **2 – 4** **2 - 4**	**7** **7** **7** **7**	**/**
GP ABUTMENTS (engaging / non engaging): indicated for restorations of single and multiple implants. They can be modified with a drill and they can be used as definitive abutment.	**4,5,6** **4.5** **4.5**	**1.2 –1.5 – 2.1** **1.5** **1.5**	**11** **10.5** **10.5**	**0°** **15°** **25°**

	JDICON Plus ABUTMENTS			
SHORT DESCRIPTION	**DIAMETER (mm)**	**GINGIVAL COLLAR HEIGHT (mm)**	**POST HEIGHT (mm)**	**ANGULATION**
ANATOMIC ABUTMENTS: indicated for cemented prosthesis of single and multiple units. The anatomic abutment has an anatomical festoon preparation of the cervical margin that ensure lesser need of abutment preparation.	**5**	**1.5 – 3** **1.5 – 3**	**7.5** **7.5**	**15°** **25°**
CONICAL ABUTMENTS: indicated for screwed-in prosthesis. Conical abutments, available in both straight and angulated models are intended to be used only for multi-unit restorations. The "tissue lovers" models are characterized by a concave abutment profile.	**4.8**	**1.5 -3- 4** **2.5 – 3.5** **2.5-3.5**	**2.2** **2.2** **2.2**	**0°** **17°** **30°**
BALL ABUTMENTS: indicated to be directly screwed into the fixture placed in fully edentulous jaws to support an overdenture retained with ball or hemi-ball anchoring.	**4**	**1.5 -3-5**	**3.2**	**/**
EMI ABUTMENTS: indicated to be directly screwed into the fixture placed in fully edentulous jaws to support an overdenture retained with ball or hemi-ball anchoring	**3.7**	**1.5 -3-5**	**1.6**	**/**
OCTA ABUTMENTS: indicated for screwed-in prosthesis. Octa abutments are intended to be used only for multi-unit restorations, with no angulation correction. Octa abutment top face is characterized by an octagonal connection.	**3.8**	**1.5-3-4-5-6**	**2**	**/**

5. Indications for Use

JDentalCare Dental Implant System, family names JDEvolution, JDEvolution Plus, JDIcon, JDIcon Plus, is intended to replace missing masticatory functional units (teeth) within the maxilla or mandible.
JDentalCare Dental Implant System is comprised of dental implant fixtures and prosthetic devices. It provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare Dental Implant System is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
Implants 20 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
JDentalCare implant system JDIcon 2.75mm D Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors for single stage or two stage procedures. It is for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations.

The difference in indications for use statement between subject device and primary predicate device is only related to the specification related to Implants 20 mm length; this difference is acceptable since primary predicate device didn't have implants with length of 20 mm

6. Comparison of the technological characteristics with the predicate device

The *JDentalCare Dental Implant System*, family names *JDEvolution plus, JDEvolution, JDIcon, JDIcon plus,* are substantially equivalent to the devices legally marketed in US listed in the tables below.
For the endosseous dental implant fixtures and implant abutment the considered "predicate" devices are the following:

Applicant	*Device name*	*510(k) Number*	*Product code*
J DENTAL CARE S.r.l.	JDentalCare® Implant System JDIcon®	K182081	DZE NHA

Moreover, the following reference devices have been considered:

Applicant	*Device name*	*510(k) Number*	*Product code*
J DENTAL CARE S.r.l.	JDentalCare® Implant System JDEvolution®	K143142	DZE NHA
Adin Dental Implants Systems Ltd.	TOUAREG CloseFit™ UNP 2.75mmD	K153111	DZE NHA
Nobel Biocare AB	TiUltra Implants and Xeal Abutments	K202344	DZE
Nobel Biocare AB	NobelSpeedy® Groovy	K160119	DZE
Nobel Biocare AB	Nobel Active	K142260	DZE NHA
Nobel Biocare AB	Nobel Biocare Healing Cap Multi-Unit Titanium	K171142	NHA
MIS Implants Technologies	MIS V3 Conical Connection Dental Implant System	K163349	DZE NHA

The devices JDIcon®, has been considered as basic predicate device, because the endosseous implants and abutments have similar dimensions and features to many proposed devices; the endosseous implants have the same surface treatment (SLA) of the proposed device and, for the majority of them several other comparable components / abutment combinations.

Below the tables that compare subject and predicate devices

Table 1. Comparison Table for General Characteristics of Dental Implants and abutments

	Proposed Device	**Predicate Device**	**Reference Device**					
	JDentalCare® Dental Implant System	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System (K143142)**	**TOUAREG CloseFit™ UNP 2.75mmD (K153111)**	**TiUltra implants and Xeal Abutments K202344**	**Nobel Speedy (K160119)**	**NobelActive K142260**	**Equivalence Discussion**
Regulation Number:	872.3640 – Endosseous dental implant.	872.3640 – Endosseous dental implant.	872.3640 – Endosseous dental implant.	872.3640 – Endosseous dental implant.	872.3640 – Endosseous dental implant.	872.3640 – Endosseous dental implant.	872.3640 – Endosseous dental implant.	Same Regulation Number
Classification:	II	II	II	II	II	II	II	Same Classification
Product Code:	DZE (implant) NHA (Abutments)	DZE (implant) NHA (Abutments)	DZE (implant) NHA (Abutments)	DZE (implant) NHA (Abutments)	DZE (implant) NHA (Abutments) PNP (Digital Dentistry workflow)	DZE	DZE (implant) NHA (Abutments)	Same Product Code
Intended Use:	JDentalCare Dental Implant System, family names JDEvolution, JDEvolution Plus, JDIcon, JDIcon Plus, is intended to replace missing masticatory functional units (teeth) within the maxilla or mandible. JDentalCare Dental Implant System is comprised of dental implant fixtures and	JDentalCare® Implant System JDIcon® is intended to replace missing masticatory functional units (teeth) within the maxilla or mandible. JDentalCare® implant system JDIcon® is comprised of dental implant fixtures and prosthetic devices. It	JDental Care® implant system is intended for surgical placement in the upper or lower jaw. JDental Care® implant system is comprised of dental implant fixtures and prosthetic devices. JDental Care® implant system provides a means for prosthetic attachment in single tooth	TOUAREG CloseFit™ UNP 2.75mmD implants are indicated to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. For single-stage or two-stage procedures. For immediate implantation in extraction sites or	NobelActive TiUltra NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive TiUltra 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	NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.	Same Intended Use

	prosthetic devices. It provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare Dental Implant System is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore	provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare® implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading,	restoration and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDental Care® implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and the functional load is appropriate. The TOUAREG CloseFit™ UNP 2.75mmDDental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors.	technique in combination with immediate, early or delayed loading protocols,recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only. NobelReplace CC TiUltra NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or non-splinted applications. The NobelReplace CC TiUltra implant may be placed	are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	NobelActive® 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. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for	

	chewing function. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate. Implants 20 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. JDentalCare implant system JDIcon 2.75mm D Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors for single stage or two stage procedures. It is for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge	in order to restore chewing function. JDentalCare® implant system JDicon® 2.75mm Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors for single-stage or two-stage procedures. It is for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one- applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.			immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. NobelParallel CC TiUltra NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function. NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2- stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with <7mm length are for delayed loading only when appropriate stability has been achieved. MUA Xeal The MUA Xeal is a premanufactured		single unit restorations only	

	situations.				prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. On1 Base Xeal The On1 Base Xeal device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base Xeal, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiplecomponents of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.			

Table 2 - Comparison Table for **Endosseous Implants** fixture of ***JDentalCare® Dental Implant System*** family named ***JDEvolution®Plus***

	Proposed Device	**Predicate device**	**Reference device**	**Reference Device**	**Reference device**	**Reference Device**	
	JDentalCare® Dental Implant System JDEvolution® Plus	**JDentalCare® JDIcon® (K182081)**	**JDentalCare® JDEvolution (K143142)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Speedy (K160119)**	**Equivalence Discussion**
Indication	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Same Indication
Placement method	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Same Placement Method
Materials	Titanium grade 4	Titanium grade 4 Titanium grade 5 (for Ø2.75 mm)	Titanium grade 4 Titanium grade 5 (for Ø 3.25mm)	Titanium grade 4 Titanium grade 5	Titanium grade 4 Titanium grade 5	Titanium	Same Materials
Design – Mechanical features							
Shape	Two pieces Tapered screw Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw External Hexagon	Same shape of predicate device Similar shape of reference device
Thread of the body	Double Thread Lead 1.2mm Lead 0.6mm outline: trapezoidal	Double Thread Lead 1.2mm (thread space) outline: trapezoidal	Double Thread Lead 1.2mm (thread space) outline: trapezoidal	Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads	Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads	Single lead thread with groove	Same thread of predicate and reference devices
Neck features	Collar with Crestal grooves lead 0.3 mm	Collar with crestal grooves lead 0.25mm (forØ2.75mm)	Collar with Crestal grooves lead 0.3 mm	Crestal grooves	Crestal grooves	No crestal grooves	Same neck features of predicate devices

	Proposed Device	**Predicate device**	**Reference device**	**Reference Device**	**Reference device**	**Reference Device**	
	JDentalCare® Dental Implant System JDEvolution® Plus	**JDentalCare® JDIcon® (K182081)**	**JDentalCare® JDEvolution (K143142)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Speedy (K160119)**	**Equivalence Discussion**
Design – Surface features							
Body	SLA (Sandblasting followed by acid etching)	SLA (Sandblasting followed by acid etching)	DAE (Double Acid Etching)	Ti Unite surface Treatment	Ti Ultra	Ti Unite surface Treatment	Similar surface treatment of predicate device
Neck	Fully SLA treated or anodization (1.5 mm or 2.5 mm)	SLA treatment or Machined	N/A	Ti Unite surface Treatment	Anodic oxidation on collar and inside the connection	Ti Unite surface Treatment	Same neck treatment (SLA) of reference device JDIcon (K182081) Same neck treatment (anodization) of reference device
Design - Dimensions							

	Proposed Device	**Predicate device**	**Reference device**	**Reference Device**	**Reference device**	**Reference Device**	
	JDentalCare® Dental Implant System JDEvolution® Plus	**JDentalCare® JDIcon® (K182081)**	**JDentalCare® JDEvolution (K143142)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Speedy (K160119)**	**Equivalence Discussion**
Diameter (mm)	Fully Treated 3.7/4.3/5 Anodized Collar (1.5mm) + Pitch 1.2 3.7/4.3/5/6 Anodized Collar (2.5mm) + Pitch 1.2 4 Anodized Collar (1.5mm) + Pitch 0.6 4	2.75/3.9/4.3/5	3.25/3.7/4.3/5/6	3.0, 3.5, 4.3, 5.0, 5.5	TiUltra 3.0, 3.5, 4.3, 5.0, 5.5	4	Similar diameters of predicate devices (no worst case dimensions)
Length(*)	Fully Treated 18 Anodized Collar (1.5mm) + Pitch 1.2 8/10/11.5/13/15/18 Anodized Collar (2.5mm) + Pitch 1.2 11.5/13/15/18/20 Anodized Collar (1.5mm) + Pitch 0.6 8/10/11.5/13/15/18	8/10/11.5/13/15	8/10/11.5/13/15	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0	TiUltra 7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0	20/22/25	Same length of predicate / reference devices
Design – Connection System							

	Proposed Device	**Predicate device**	**Reference device**	**Reference Device**	**Reference device**	**Reference Device**	
	JDentalCare® Dental Implant System JDEvolution® Plus	**JDentalCare® JDIcon® (K182081)**	**JDentalCare® JDEvolution (K143142)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Speedy (K160119)**	**Equivalence Discussion**
Type	Internal Hexagon	Conical connection with internal hexagon	Internal Hexagon	Internal conical connection with hex interface	Internal conical connection with hex interface	External Hexagon	Same connection of predicate device
Platform size / Abutment interface (mm)	Ab.Int. / Diameter 3.4 / 3.7 3.4 / 4.0 3.4 / 4.8 3.4 / 5.0 3.4 / 6.0	Ab Int / Diameter 2.3 / 2.75 3.4 / 3.90 3.4 / 4.30 3.4 / 5.00	Ab.Int. / DIameter 3.4 / 3.7 3.4 / 4.3 3.4 / 5.0 3.4 / 6.0	Ab.Int. / DIameter2.5 / 3.0 3.0 / 3.5 3.4 / 4.3 3.4 / 4.9 4.4 / 5.5	Ab.Int. / DIameter2.5 / 3.0 3.0 / 3.5 3.4 / 4.3 3.4 / 5.0 4.4 / 5.5	Ab Int / Diameter 4.1 / 4	Same platform size / abutment interface of predicate devices
Packaging							
kind of package	plastic vial + blister	plastic vial + blister	plastic vial + blister	Polyethylene terephthalate (PET) vial with high density poly ethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside a cardboard box (protective packaging).	Polyethylene terephthalate (PET) vial with high density poly ethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside a cardboard box (protective packaging).	Polyethylene terephthalate (PET) vial with high density poly ethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside a cardboard box (protective packaging).	Same packaging of predicate device

	Proposed Device	**Predicate device**	**Reference device**	**Reference Device**	**Reference device**	**Reference Device**	
	JDentalCare® Dental Implant System JDEvolution® Plus	**JDentalCare® JDIcon® (K182081)**	**JDentalCare® JDEvolution (K143142)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Speedy (K160119)**	**Equivalence Discussion**
Sterile	Yes Gamma Radiation	Yes Gamma Radiation	Yes Gamma Radiation	Gamma Radiation (SAL 10-6)	Gamma Radiation (SAL 10-6)	Gamma Radiation (SAL 10-6)	Same sterilization of predicate device

Table 3 - Comparison Table for **Abutments** of ***JDentalCare® Dental Implant System*** family named ***JDEvolution®Plus***

	Proposed device	Reference device	Reference device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System JDEvolution®Plus**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit Titanium (K171142**	**NobelActive (K142260)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Design							
Healing abutment	Ø5 - height: 4,6,9 mm Material: Titanium grade 5	Ø4 - height: 3,5,7 mm Ø5 - height: 3,5,7 mm Ø6 - height: 3,5,7 mm Material: Titanium grade 5	N/A	N/A	Ø3.2 – 6 mm height: 3,5,7mm Material: Titanium grade 5	N/A	Same dimension, geometry and material for subject and predicate device (K143142) The healing abutment Height 9 mm can be considered a non-significant modification since this height is not relevant for loading
Surface treatment	Anodization	No treatment	N/A	N/A	Anodization	N/A	Same surface treatment between subject and reference device Nobel Active (K142260) The anodization does not impact biocompatibility
Temporary abutments (non rotating / rotating)	Temporary abutments engaging and non-engaging models Ø3.1 - height: 10mm Material: Titanium grade 5	Available both non rotating / rotating models Ø3.1 - height: 10mm Material: Titanium grade 5	N/A	N/A	Temporary abutments engaging and non-engaging models Ø not published – height 10 mm Material: Titanium grade 5	N/A	Same dimension, geometry and material for subject and predicate device (K143142) and reference device Nobel Active (K142260)
Surface treatment	Anodization	No treatment	N/A	N/A	Anodization	N/A	Same surface treatment between subject and reference device Nobel Active (K142260)

	Proposed device	Reference device	Reference device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System JDEvolution®Plus**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit Titanium (K171142**	**NobelActive (K142260)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Straight abutment	Ø5 mm Collar height 2 - 4 mm Ø4 mm Collar height 0.5 mm Material: Titanium grade 5	Ø4, 5, 6 mm Collar height 2 - 4 mm Material: Titanium grade 5	N/A	N/A	Straight Ø not published Collar Height 0,5 – 1 - 1,5 – 2 – 3 – 4,5 mm Material: titanium grade 5	N/A	Same dimension, geometry and material for subject and predicate device (K143142) Similar dimension, geometry and material for subject and reference device Nobel Active (K142260) Comparable results for mechanical tests
Surface treatment	Anodization (both abutment and prostethic screw or only prosthetic screw)	No treatment	N/A	N/A	Anodization	N/A	Same surface treatment between subject and reference device Nobel Active (K142260)
GP Abutment	GP abutments straight (Ø4, 5mm) 15°, 25° angled (Ø4.5mm) Height 10 mm Material: Titanium grade 5	GP abutments straight (Ø4, 5, 6 mm) Height 7 mm Material: titanium grade 5	N/A	N/A	15° angled Ø not published Height: 8, 8.5,9.5, 10, 11 mm Material: titanium grade 5	25° angled abutment (Ø4.8, 5.5, 5.8 mm) Height (gingival) 1 – 2 - 3 mm Material: titanium grade 5	Straight GP Abutment Same dimension, geometry and material for subject and predicate device (K143142) Angled GP Abutment Same dimension, geometry and material for subject and reference devices NobelActive (K142260) and MIS V3 (K163349) Comparable results for mechanical tests

	Proposed device	Reference device	Reference device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System JDEvolution®Plus**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit Titanium (K171142**	**NobelActive (K142260)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Surface treatment	Anodization only for prosthetic screw	No treatment	N/A	N/A	Anodization on the top	Anodization	Same surface treatment between subject and reference devices NobelActive (K142260) and MIS V3 (K163349)
Conical Abutments	Ø4.8mm Angle 0° - collar height 1-7-9mm Angle 0° anodized-collar height 1.5-3-4 - 5mm Angle 17° anodized-collar height2.5-3.5 mm Angle 30° anodized-collar height 2.5 – 3.5 – 5 mm Material: Titanium grade 5	Ø4.8mm Angles 0 – 17° – 30° angle 0° - collar height 1,5 – 2 – 3 – 4 mm angle 17° - collar height 2,5 – 3,5 mm angle 30° - collar height 2,5 – 3,5 mm Material: Titanium grade 5	MUA Xeal Ø not published Angles 0 – 17° – 30° Angle 0° collar height: 1.5, 2.5, 3.5, 4.5 Angle 17° - collar height: 2.5, 3.5 Angle 30° - collar height: 3.5, 4.5 Material: Titanium grade 5	N/A	N/A	N/A	Same dimension, geometry and material for subject and predicate device (K143142) Similar dimension, geometry and material for subject and reference device TiUltra implants and Xeal abutments (K202344) Comparable results for mechanical tests
Surface treatment	No treatment or anodization	No treatment	Anodization	N/A	N/A	N/A	Same surface treatment between subject and reference device TiUltra implants and Xeal abutments (K202344)

	Proposed device	Reference device	Reference device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System JDEvolution®Plus**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit Titanium (K171142**	**NobelActive (K142260)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Healing CAP	Ø5 mm Available in 2 heights: 6 – 9 mm Material: Titanium grade 5 Surface treatment: Anodization	Ø4.8 mm Height: 3 mm Material: Titanium grade 5 Surface treatment: No treatment	N/A	Available in 2 diameters: 5 – 6 mm Available in 2 heights: 4.1 – 5.5 mm Material: Titanium grade 5 Surface treatment: No treatment	N/A	N/A	Same geometry and material for subject and Predicate device (K143142) Same dimension, geometry and material for subject device and Reference device (K171142) The healing cap Height 9 mm can be considered a non-significant modification since this height is not relevant for loading Anodization does not impact biocompatibility
Materials							
Materials	Titanium grade 5	Titanium grade 5	N/A	Titanium grade 5	N/A	N/A	Same material
Packaging							
Sterility	Non sterile	Non Sterile	Sterile	Sterile	Sterile	Non sterile	Not sterile both subject and predicate device (K143142)

Table 4 - Comparison Table for **Abutments** of ***JDentalCare® Dental Implant System*** families named ***JDEvolution (related to 3.25mm implants)***

	Proposed device	**Reference device**	**Reference device**	
Features	**JDentalCare® Dental Implant System JDEvolution (3.25mm)**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**Equivalence DIscussion**
Design				
Conical Abutments	Ø4.8mm Angle 0° - collar height 3 mm Angle 17° - collar height 3.5 mm Angle 30° - collar height 3.5 mm ANODIZED: Angle 0° - collar height 1.5 - 3 mm Angle 17° - collar height 2.5 –3.5 mm Angle 30° - collar height 2.5 – 3.5 mm Material: Titanium grade 5	Ø4.8mm Angles 0 – 17° – 30° Height from 1 to 4 mm depending on the model. In detail: angle 0° - collar height 1,5 – 2 – 3 – 4 mm angle 17° - collar height 2,5 – 3,5 mm angle 30° - collar height 2,5 – 3,5 mm	Ø not published MUA Xeal Angle 0° – collar height: 1.5, 2.5, 3.5, 4.5 Angle 17° - collar height: 2.5, 3.5 Angle 30° - collar height: 3.5, 4.5 Material: Titanium grade 5	Same dimension, geometry and material for subject and predicate device (K143142) Same dimension, geometry and material for subject and reference device (K202344) Comparable results for mechanical tests
Surface treatment	No treatment or anodization (both abutment and prostethic screw or only prosthetic screw)	No treatment	Anodization	Same surface treatment as predicate / reference device
Materials				
Materials	Titanium grade 5	Titanium grade 5	Titanium (commercially pure)	Same materiale
Packaging				
Sterility	Non sterile	Non Sterile	Sterile	Not sterile both subject and predicate device (K143142)

Table 5 - Comparison Table for **Endosseous Implants** fixture of ***JDentalCare® Dental Implant System*** family named ***JDIcon***

	Proposed Device	**Predicate device**	**Reference device**	
	JDentalCare® Dental Implant System Family JDIcon	**JDentalCare® Implant System JDIcon® (K182081)**	**TiUltra implants and Xeal Abutment (K202344)**	**Equivalence Discussion**
Indication	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Same Indication of predicate device
Placement method	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Same Placement Method of predicate device
Materials	Titanium grade 4	Titanium grade 4 Titanium grade 5 (forØ2.75mm)	Titanium grade 4 Titanium grade 5	Same Materials of predicate device
Design – Mechanical features				
Shape	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Same Shape of predicate device Similar shape of reference device
Thread of the body	Double Thread Lead 1,2mm (thread space) outline: trapezoidal	Double Thread Lead 1,2mm (thread space) outline: trapezoidal	Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads	Same thread of predicate devices Similar thread of reference device
Neck features	No crestal grooves for diameters included in this submission	Collar with crestal grooves lead 0,25 mm (for Ø2.75 mm) No crestal grooves for other diameters	Crestal grooves	Same neck features of predicate devices
Design – Surface features				
Body	SLA (Sandblasting followed by acid etching)	SLA (Sandblasting followed by acid etching)	Ti Ultra treatment on body	Same surface treatment of predicate device
Neck	SLA or Machined	SLA or Machined	Anodic oxidation on collar and inside the connection	Same neck treatment (SLA or machined) of predicate device
Design – Dimensions				
Diameter (mm)	3.9	2.75/3.9/4.3/5	3.0, 3.5, 4.3, 5.0, 5.5	Same diameter of predicate device

	Proposed Device	**Predicate device**	**Reference device**	
	JDentalCare® Dental Implant System Family JDIcon	**JDentalCare® Implant System JDIcon® (K182081)**	**TiUltra implants and Xeal Abutment (K202344)**	**Equivalence Discussion**
Length	18	8/10/11.5/13/15	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0	Same length of reference device for 18 mm
Design – Connection System				
Type	Conical connection with internal hexagon	Conical connection with internal hexagon	Internal conical connection with hex interface	Same connection of predicate device
Platform size / Abutment interface (mm)	Ab.Int. / Diameter 3.4 3.90	Ab.Int. / Diameter 2.3 2.75 3.4 3.90 3.4 4.30 3.4 5.00	Ab.Int. / Diameter 2.5 3.0 3.0 3.5 3.4 3.9 4.4 5.1	Same platform size / abutment interface of predicate device
Packaging				
kind of package	plastic vial + blister	plastic vial + blister	plastic vial + blister	Same packaging of predicate device
Sterile	Yes Gamma Radiation	Yes Gamma Radiation	Yes Gamma Radiation	Same sterilization of predicate device

Table 6 - Comparison Table for **Abutments** of ***JDentalCare® Dental Implant System*** families named ***JDIcon***

	Proposed device	Predicate device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon (added abutments)**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Design						
Healing abutment	Ø5 - height: 9 mm Material: Titanium grade 5	Ø4 - height: 3,5,7 mm Ø5 - height: 3,5,7 mm Ø6 - height: 3,5,7 mm Material: Titanium grade 5	/	/	/	Same geometry and material for subject and predicate device (K182081) The healing abutment Height 9 can be considered a non-significant modification since this height is not relevant for loading
Surface treatment	No treatment	No treatment	/	/	/	Same surface treatment for subject and predicate device (K182081)
Temporary abutments (non rotating / rotating)	Temporary Abutment Non Engaging for Welding JDIcon Ø4.4 – Height 10mm Material: Titanium grade 5	Temporary abutments engaging and non-engaging models Ø3.8 – Height 10mm Material: Titanium grade 5	/	/	/	Similar dimension, same geometry and material for subject and predicate device (K182081)
Surface treatment	No treatment	No treatment	/	/	/	Same surface treatment for subject and predicate device (K182081)

	Proposed device	Predicate device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon (added abutments)**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Anatomic abutment	Ø5.5mm Angulated 15°: Collar height 1,5-3mm Angulated 25°: Collar height 1,5-3mm Material: Titanium grade 5	/	Ø5.5mm Angulated 15°: Collar height 1,5-3mm Material: Titanium grade 5	/	Angled 25° Angulated abutment (Ø4.8, 5.5, 5.8 mm) Height (gingival) 1 – 2 - 3 mm Material: Titanium grade 5	Angulated 15° Same dimension, geometry and material for subject and reference device (K143142) Angulated 25° Same dimension, geometry and material for subject and reference device MIS V3 (K163349) Comparable results for mechanical tests
Surface treatment	No treatment	/	No treatment	/	Anodization	Same surface treatment between subject reference device (K143142)

	Proposed device	Predicate device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon (added abutments)**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Conical Abutments	Ø4.8mm Angle 17° - collar height 2.5-3.5 mm Angle 30° - collar height 2.5 – 3.5mm Material: Titanium grade 5	/	Ø4.8mm Angle 0° - collar height 1,5 – 2 – 3 – 4 mm Angle 17° - collar height 2,5 – 3,5 mm Angle 30° - collar height 2,5 – 3,5 mm Material: Titanium grade 5	MUA Xeal Ø not published Angles 0 – 17° – 30° Angle 0° collar height: 1.5, 2.5, 3.5, 4.5 Angle 17° - collar height: 2.5, 3.5 Angle 30° - collar height: 3.5, 4.5 Material: Titanium grade 5	/	Same dimension, geometry and material for subject and reference device (K143142) Comparable results for mechanical tests
Surface treatment	No treatment	/	No treatment	/	/	Same surface treatment between subject and reference device (K143142)

	Proposed device	Predicate device	Reference device	Reference Device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon (added abutments)**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**TiUltra implants and Xeal Abutments (K202344)**	**MIS V3 Conical Connection Dental Implant System (K163349)**	**Equivalence DIscussion**
Straight Abutments	Ø3.5 mm Collar height 1-2 mm	(straight abutments) Ø4, 5, 6 mm Collar height 2 - 4 mm Material: Titanium grade 5	/	/	/	Similar dimension, geometry and material for subject and predicate device JDIcon (K182081) Comparable results for mechanical tests
Surface treatment	No treatment	No treatment	/	/	/	Same surface treatment as predicate device
Materials						
Materials	Titanium grade 5	Titanium grade 5	Titanium grade 5	Titanium grade 5	/	Same material between subject and predicate / reference devices
Packaging					/	
Sterility	Non sterile	Non Sterile	Non Sterile	Sterile	Non Sterile	Not sterile both subject and predicate / reference devices

Table 7 - Comparison Table for **Abutments** of ***JDentalCare® Dental Implant System*** families named ***JDIcon 2.75***

	Proposed device	**Predicate device**	**Reference device**	
Features	**JDentalCare JDIcon (2.75mm) (added abutments)**	**JDentalCare® Implant System JDIcon (K182081)**	**Adin Dental Implants. TOUAREG CloseFit™ UNP 2.75mmD (K153111)**	**Equivalence DIscussion**
Design				
GP abutment	Ø4.0 mm Heigth 10 mm Angulated 15°: Material: Titanium grade 5	Ø3.2, 4.0 mm Heigth 10 mm Material: Titanium grade 5	UNP Angled Abutment 15° No End Line Ø, height not published Angled 15° Material: Titanium grade 5	Similar dimension, geometry and material for subject and reference device (K153111) Comparable results for mechanical tests
Surface treatment	No treatment	No treatment	No treatment	Same surface treatment between subject and predicate / reference devices
Conical Abutments	Ø4.8 mm Angle 0° - collar height 1.5 Angle 17° - collar height 2.5- mm Material: Titanium grade 5	/	UNP Straight Slim Abutment No End Line UNP Angled Abutment 15° No End Line Ø, height not published Angled 0° - 15° Material: Titanium grade 5	Similar dimension, geometry and material for subject and reference device Comparable results for mechanical tests
Surface treatment	No treatment	/	No treatment	Same surface treatment between subject and reference devices
Materials				
Materials	Titanium grade 5	Titanium grade 5	Titanium grade 5	Same material between subject and predicate / reference devices
Packaging				

	Proposed device	Predicate device	Reference device	
Features	**JDentalCare JDIcon (2.75mm) (added abutments)**	**JDentalCare® Implant System JDIcon (K182081)**	**Adin Dental Implants. TOUAREG CloseFit™ UNP 2.75mmD (K153111)**	**Equivalence DIscussion**
Sterility	Non sterile	Non Sterile	Non Sterile	Not sterile both subject and predicate / reference devices

Table 8 - Comparison Table for **Endosseous Implants** fixture of family named ***JDIcon® Plus***

	Proposed Device	**Predicate device**	**Reference Device**	**Reference device**	**Equivalence Discussion**
	JDentalCare® Dental Implant System JDIcon® Plus	**JDentalCare® Implant System JDIcon (K182081)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	
Indication	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Immediate or delayed load	Same Indication
Placement method	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Dual or single stage surgery	Same Placement Method
Materials	Titanium grade 4	Titanium grade 5 (for Ø2.75 mm) Titanium grade 4	Titanium grade 4 Titanium grade 5	Titanium grade 4 Titanium grade 5	Same Materials
Design – Mechanical features					
Shape	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Two pieces Tapered screw Conical with Internal Hexagon	Similar shape of predicate and reference devices
Thread of the body	Double Thread Lead 1,2mm (for diameter 3.7 - 4.3 – 5.0) Single Thread Lead 0,8mm (for diameter 3.5 - 4.0 – 4.5) (thread space) outline: trapezoidal	Double Thread Lead 1,2mm (thread space) outline: trapezoidal	Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads	Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads	Same thread of predicate devices (for 1.2 mm lead) Similar thread of predicate and reference device
Neck features	Collar with crestal grooves lead 0,3mm for diameter 3.7 - 4.3 – 5.0 and thread for diameters 3.5 - 4.0 – 4.5	Collar with crestal grooves lead 0.25 mm (for Ø2.75 mm)	Crestal grooves	Anodic oxidation on collar and inside the connection	Same neck features of predicate devices (for fully treated) Similar neck features of reference device (for anodized neck)
Design – Surface features					
Body	Sandblasting followed by acid etching	Sandblasting followed by acid etching	Ti Unite surface Treatment	Ti Ultra	Same surface treatment of predicate device

	Proposed Device	Predicate device	Reference Device	Reference device	Equivalence Discussion
	JDentalCare® Dental Implant System JDIcon® Plus	**JDentalCare® Implant System JDIcon (K182081)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	
Neck	Anodization or Fully treated SLA	Sandblasting followed by acid etching (for fully threated version)	Ti Unite surface Treatment	Anodic oxidation on collar and inside the connection	Same neck treatment (SLA) of predicate device Similar neck treatment (anodization) of reference device
Design – Dimensions					
Diameter (mm)	3.7/4.3/5 3.5/4/4.5	2.75/3.9/4.3/5	3.0, 3.5, 4.3, 5.0, 5.5	3.0, 3.5, 4.3, 5.0, 5.5mm	Similar dimensions of predicate devices (no worst case dimensions)
Length(*)	8/10/11.5/13/15/18 8.5/10/11.5/13	8/10/11.5/13/15	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm	Same length of predicate and reference devices
Design – Connection System					
Type	Conical connection with internal hexagon	Conical connection with internal hexagon	Internal conical connection with hex interface	Internal conical connection with hex interface	Same connection of predicate device
Platform size / Abutment interface (mm)	Ab.Int. / DIameter 3.1 3.40 3.1 3.60 3.1 3.76 3.1 4.00 3.1 4.80	Ab.Int. / DIameter2.3 2.75 3.4 3.90 3.4 4.30 3.4 5.00	Ab.Int. / DIameter2.5 / 3.0 3.0 / 3.5 3.4 / 4.3 3.4 / 4.9 4.4 / 5.5	Ab.Int. / diameter 2.5 3.0 3.0 3.5 3.4 3.9 4.4 5.1	similar platform size / abutment interface of predicate device
Packaging					

	Proposed Device	Predicate device	Reference Device	Reference device	Equivalence Discussion
	JDentalCare® Dental Implant System JDIcon® Plus	**JDentalCare® Implant System JDIcon (K182081)**	**Nobel Active (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	
kind of package	plastic vial + blister	plastic vial + blister	Polyethylene terephthalate (PET) vial with high density poly ethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside a cardboard box (protective packaging).	Double vial	Same packaging of predicate device
Sterile	Yes Gamma Radiation	Yes Gamma Radiation	Gamma Radiation (SAL 10-6)	Yes Gamma Radiation	Same sterilization of predicate device

Table 9 - Comparison Table for **Abutments** of family named ***JDIcon® Plus***

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
Design								
Healing abutment	Ø4 - height: 3,5,7 mm Ø5 - height: 3,5,7 mm Ø6 - height: 3,5,7 mm Ø7.5 - height: 3,5 mm Material: Titanium grade 5	Ø4 - height: 3,5,7 mm Ø5 - height: 3,5,7 mm Ø6 - height: 3,5,7 mm Material: Titanium grade 5	/	Ø3.2 – 6 mm height: 3,5,7 Material: Titanium grade 5	/	/	N/A	Same geometry and material for subject and predicate device (K182081) and reference device (K142260) The healing abutment diameter 7.5 can be considered a non-significant modification since this height is not relevant for loading
Surface treatment	Anodization	No treatment	/	Anodization	/	/		Same surface treatment between subject and reference device Anodization does not impact since biocompatibility tests showed that anodization is biocompatible

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
Temporary abutments (non rotating / rotating)	Temporary abutments engaging and non-engaging models Ø3.7 – Height 10mm Material: Titanium grade 5	Temporary abutments engaging and non-engaging models Ø3.8 – Height 10mm Material: Titanium grade 5	/	Temporary abutments engaging and non-engaging models Ø not published – height 10 mm Material: Titanium grade 5	/	/		Same dimension, geometry and material for subject and predicate device (K182081) and reference device (K142260)
Surface treatment	Anodization	No treatment	/	Anodization	/	/		Same surface treatment between subject and Nobel Active (K142260) reference device Anodization does not impact performances since biocompatibility tests showed that anodization is biocompatible

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
Straight abutment	Ø4.5, 5.0, 5.5, 6.0 mm Collar height 2 - 4 mm Material: Titanium grade 5	Ø4, 5, 6 mm Collar height 2 - 4 mm Material: Titanium grade 5	/	Straight Ø not published Collar Height 0,5 – 1 - 1,5 – 2 – 3 – 4,5 mm Material: titanium grade 5	/	/	/	Same dimension, geometry and material for subject and predicate device (K182081) Similar dimension, geometry and material for subject and reference device Comparable results for mechanical tests
Surface treatment	Anodization	No treatment	/	Anodization	/	/	/	Same surface treatment between subject and Nobel Active (K142260) reference device Anodization does not impact performances since biocompatibility tests showed that anodization is biocompatible
GP Abutment	GP abutments straight (Ø4, 5, 6 mm) and angled 15°, 25° (Ø4.5 mm) Height 10.5, 11mm Material: Titanium grade 5	GP abutments straight (Ø3.2, 4, 5, 6 mm) Height 10, 10.5mm Material: Titanium grade 5	/	15° angled Ø not published Height: 8, 8.5,9.5, 10, 11 mm Material: titanium grade 5	/	/	25° angled abutment (Ø4.8, 5.5, 5.8 mm) Height (gingival) 1 – 2 - 3 mm	Straight GP Abutment Same dimension, geometry and material for subject and predicate device (K182081) Angled GP Abutment Same dimension, geometry and material for subject and

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
							Material: Titanium grade 5°	reference devices (K142260), (K163349)
Surface treatment	Anodization	No treatment	/	Anodization	/	/	Anodization	Same surface treatment between subject and Nobel Active (K142260) reference device Anodization does not impact performances since biocompatibility tests showed that anodization is biocompatible
Anatomic Abutments	Ø5 mm Angulated 15°: Collar height 1,5-3mm Angulated 25°: Collar height 1,5-3mm ° Material: Titanium grade 5	/	Ø5.5mm Straight: Collar height 1,5-3mm Angulated 15°: Collar height 1,5-3mm Angle 0° - 15° Material: Titanium grade 5	/	/	/	25° angled abutment (Ø4.8, 5.5, 5.8 mm) Height (gingival) 1 – 2 - 3 mm	Same dimension, geometry and material for subject and reference device (K143142) Angled Anatomic Abutment Same dimension, geometry and material for subject and reference device (K163349) Comparable results for mechanical tests

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
Surface treatment	Anodization	/	No treatment	/	/	/	Anodization	Same surface treatment between subject and Nobel Active (K142260) reference device Anodization does not impact performances since biocompatibility tests showed that anodization is biocompatible
Conical Abutments	Ø4.8 mm Angle 0° - collar height 1.5 – 3 - 4 mm Angle 17° - collar height 2.5 – 3.5 mm Angle 30° - collar height 2.5 – 3.5 mm Material: Titanium grade 5	Ø4.8 mm Angle 0° - collar height 1.5 – 3 mm Material: Titanium grade 5	/	/	MUA Xeal Ø not published Angles 0 – 17° – 30° Angle 0° - collar height: 1.5, 2.5, 3.5, 4.5 Angle 17° - collar height: 2.5, 3.5 Angle 30° - collar	/		Similar dimension, geometry and material for subject and predicate device (K143142) and reference device Comparable results for mechanical tests

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
					height: 3.5, 4.5 Material: Titanium grade 5			
Surface treatment	Anodization	No treatment	/	/	Anodization	/		Same surface treatment between subject and reference device (K202344) Anodization does not impact performances since biocompatibility tests showed that anodization is biocompatible
Ball Abutments	Ø4 mm Height: 1.5 – 3 – 5 mm Material: Titanium grade 5	Ø3.7 mm Height: 1.5 – 3 – 5 mm Material: Titanium	Ø4 mm Height: 1.5 – 3 – 5 mm Material: Titanium grade 5	/	/	/	Height: 1 – 2 – 3 -4 – 5 mm Material: Titanium gr 5	Similar dimension, same geometry and material for subject and predicate device (K182081) Same dimension, same geometry and material for subject and reference device (K143142)
Surface treatment	No treatment	No treatment	No treatment	/	/	/	TiN Coating	Same surface treatment as predicate device (K182081)

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
Emi Abutments	Ø3.7 mm Height: 1.5 – 3 – 5 mm Material: Titanium grade 5	Ø3.7 mm Height: 1.5 – 3 – 5 mm Material: Titanium	Ø3.7 mm Height: 1.5 – 3 – 5 mm Material: Titanium gr 5	/	/	/	Height: 1 – 2 – 3 -4 – 5 mm Material: Titanium gr 5	Same dimension, geometry and material for subject and predicate device (K182081) and Reference device (K143142)
Surface treatment	No treatment	No treatment	No treatment	/	/	/	TiN Coating	Same surface treatment as predicate device (K182081)
Octa Abutments	Ø3.8 mm Available in 5 heights: 1.5 – 3- 4 – 5 – 6 mm Material: Titanium grade 5 Surface treatment: Anodization	/	/	/	MUA Xeal Ø not published Available in 4 heights: 1.5-2.5-3.5-4.5 mm Material: Titanium grade 5	/	/	Same dimension, geometry and material for subject and Reference device (K202344)
Healing CAP	Available in 2 diameters: 4 – 5 mm Available in 2 heights: 4 – 5 mm Material: Titanium gr 5 Surface treatment: No treatment	/	Ø4.8 mm Height: 3 mm Material: Titanium grade 5 Surface treatment: No treatment	/	/	Available in 2 diameters: 5 – 6 mm Available in 2 heights: 4.1 – 5.5 mm Material: Titanium grade 5 Surface treatment: No treatment	/	Same dimension, geometry and material for subject and Reference device (K171142)

	Proposed device	Predicate device	Reference device	Reference device	Reference Device	Reference device	Reference Device	
Features	**JDentalCare® Dental Implant System Family JDIcon® Plus**	**JDentalCare® Implant System JDIcon® (K182081)**	**JDentalCare® Implant System JDEvolution (K143142)**	**NobelActive (K142260)**	**TiUltra implants and Xeal Abutments (K202344)**	**Nobel Biocare Healing Cap Multi-Unit (K171142)**	**MIS V3 Conical Connection (K163349)**	**Equivalence Discussion**
Materials	Titanium grade 5	/	Titanium grade 5	/	/	Titanium grade 5	/	Same material for subject and reference devices
Packaging								
Sterility	Non sterile	Non sterile	Non sterile	Sterile	Sterile	Sterile	Non sterile	Same material for subject, predicate and reference devices

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, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and includes:
  - o Cytotoxicity assessment according to ISO 10993-5:2009; (conducted both on implants and worst case anodized abutment)
  - o Sensitization testing according to ISO 10993-10:2010;
  - o Irritation testing according to ISO 10993-10:2010;
  - o Material – mediated pyrogenicity testing according to ISO 10993-11:2017;
  - o Acute systemic toxicity testing according to ISO 10993-11:2017.

- Packaging shelf life accelerated aging tests: testing was conducted according to ISO 11607-1, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

- Surface validation test: surface treatment is identical to predicate device. The treatment performed on implants through a sandblasting treatment followed by an acid etching treatment. Then, there is a cleaning process for the removal of residual substances. A morphological SEM analysis was performed to verify roughness and cleanliness of the surface and a cleaning process validation have been performed to verify the complete removal of materials used during manufacturing process.

- Verification of Washing Process : testing was conducted to demonstrate that no residuals substances were present on implant or abutment surface.

- Mechanical Performance Tests performed according to ISO 14801 on worst case combinations of implants and abutments representative for all the products included in current submission showed comparable results between subject device and predicate / reference devices. Mechanical Testing was conducted according to ISO 14801:2016 Dentistry — Implants — Dynamic loading test for endosseous dental implants and the FDA Guidance Document entitled, “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” (May 12, 2004).

- Gamma Ray Sterilization Validation in accordance with:
  - o ISO 11137-1:2006, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
  - o ISO 11137-2: 2013, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose

- Sterilization validation of abutments

Even though abutments are supplied not sterile, their ability to be steam sterilized before their use was verified (test performed according to ISO 17665-1:2006 Sterilization of health care products -

Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices)

- MRI environment

Non-clinical worst-case MRI review was performed to evaluate the JDENTALCARE IMPLANT SYSTEM devices in the MRI environment using scientific rationale and published literature, 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

8. Clinical data

N/A

9. Conclusions

The JDENTALCARE® DENTAL IMPLANT SYSTEM were evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics and non-clinical test data, the JDENTALCARE® DENTAL IMPLANT SYSTEM have been shown to be substantially equivalent to the predicate devices