June 26, 2020

J Dental Care S.r.l.
% Guido Bonapace
Official Correspondent
ISEMED Srl
Via P. Togliatti 19X
Imola, Bologna 40026
ITALY

Re: K182081
Trade/Device Name: JDentalCare® Implant System JDIcon®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 19, 2020
Received: June 25, 2020

Dear Guido Bonapace:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182081

Device Name
JDENTALCARE® Implant System JDIcon®

Indications for Use *(Describe)*
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 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, in order to restore chewing function.

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. 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.

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 for the JDENTALCARE Implant System

This 510(k) Summary is being submitted in accordance with the requirements of the 21 CFR 807.92.

1. General Information

Submitter: J DENTAL CARE S.r.l. is located at:
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Summary Preparation Date: June 26, 2020

2. Names

Device Name:	JDentalCare® Implant System JDIcon®
Classification Name:	Implant, Endosseous, Root-form abutment
Product Code:	DZE
Product Code (Secondary)	NHA
Regulation number:	21 CFR 872.3640
CLASS	II

3. Predicate Devices

The JDentalCare® Implant System JDIcon® is 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 "primary predicate" device is the following:

Applicant	Device name	Device Model name	510(k) Number	Product code
J Dental Care S.r.l.	JDentalCare® Implant System	JDEvolution	K143142	DZE NHA

Moreover, the following reference devices have been considered:

Applicant	Device name	510(k) Number
Adin Dental Implants Systems Ltd.	TOUAREG CloseFit™ UNP 2.75mmD	K153111
Nobel Biocare USA LLC	Nobel Active 3.0	K102436
Straumann USA LLC	Straumann® Dental Implant System SLA®	K123784

4. Device Description

JDentalCare® implant system JDIcon® is composed by a fixture and an abutment, joined together by a through screw. The connection is done through an internal hexagon.
Abutment and accessories are exclusive for JDentalCare® implant system JDIcon®.
JDentalCare® implant system JDIcon® is threaded (fully treated or with a collar of 1.5 mm), root-form dental implants, intended to provide a mean for prosthetic attachment in the rehabilitation of partial or total edentulism, in single tooth restorations or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures.
JDentalCare® implants are made of grade 4 and grade 5 titanium and are tapered.
Their surface is treated through sandblasting followed by acid etching treatment.
JDIcon® implants may be placed in the oral cavity using either a single stage surgical procedure or a two-stage surgical procedure. If a single procedure is used, the implants may be placed anywhere in the upper or lower jaw where good initial stability can be obtained.
The available dimensions of the JDentalCare® implant system JDIcon®, considering the Fully treated collar version and the machined collar version, are shown in the table below. Note the MACHINED COLLAR referenced is not implanted in bone, making the implantable length of these implants 1.5 mm less than the total implant length listed below.

JDentalCare® Implant System JDIcon® // FULLY TREATED COLLAR							
IMPLANT DIAMETER (mm)		IMPLANT LENGTHS (mm)					
	2.75	-	-	10	11.5	13	15
	3.9	-	8	10	11.5	13	15
	4.3	-	8	10	11.5	13	15
	5	-	8	10	11.5	13	15
JDentalCare® Implant System JDIcon® // MACHINED COLLAR							
IMPLANT DIAMETER (mm)		IMPLANT LENGTHS (mm)					
	3.9	-	-	10	11.5	13	15
	4.3	-	-	10	11.5	13	15
	5	-	-	10	11.5	13	15

The above listed dental implants are used with dedicated abutments, shortly described here below:

- HEALING ABUTMENT: it is used in the delayed loading technique (used when there is not a good primary stability of the bone) to close the implant connection for non-submerged healing. It helps the gum to heal properly. The abutment is screwed into the implant.
- TEMPORARY ABUTMENT (engaging/non engaging): temporary abutments are used for the fabrication of temporary screw-retained restorations. Engaging and non-engaging variants are used for single- and multiple-unit restorations, respectively.
- GP ABUTMENTS: these abutments are indicated for cemented temporary restorations of single and multiple implants. They can be modified with a drill or they can also be used as definitive abutment.
- STRAIGHT ABUTMENTS: they are 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.
- ANATOMIC ABUTMENTS: these abutments are 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.
- CONICAL ABUTMENTS: They are indicated for screwed-in prosthesis. Conical abutments are intended to be used only for multi-unit restorations, with no angulation correction.
- BALL ABUTMENTS: are indicated for overdentures with ball anchoring.
- EMI ABUTMENTS: are indicated for overdentures with hemispheric anchoring.

5. Indications for Use

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 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, in order to restore chewing function.

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. 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.

6. Performance data

Dimensions, materials and technical features are substantially equivalent to those claimed by the predicate and the references devices.
The following tests have been performed on JDentalCare® implant system JDIcon®:

BIOCOMPATIBILITY TESTS
Performed according to ISO 10993-1:2010 "Biological Evaluation of Medical Devices" (Part 1)

- Cytotoxicity
- Intracutaneous reactivity
- Delayed Hypersensitivity
- Acute Systemic Toxicity
- Bacterial Reverse Mutation

SURFACE VALIDATION TESTS
Surface treatment is performed on implants through a sandblasting treatment followed by an acid etching treatment. Then, there is a cleaning process for the removal of manufacturing residual substances. A morphological SEM analysis and a cleaning process validation have been performed.
These tests show the results of SEM analysis and the complete removal of materials used during manufacturing process.

MECHANICAL TESTS
The Mechanical test were performed in compliance with "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and "ISO 14801: 2007 - Dynamic fatigue test for endosseous dental implants". The tests demonstrated that the worst case chosen is able to resist to 5.000.000 cycles.

STERILIZATION AND PACKAGING SHELF LIFE
JDentalCare® implant system JDIcon® is sterilized with gamma ray sterilization to assure a SAL level of 10^{-6}. The validation of the sterilization process has been performed.
Shelf life granted is 5 years. The packaging is different for dental implants and abutments.
The implants are provided sterile, while the abutments are not sterile and have to be sterilized prior to use. The packaging of the implants and abutments are exactly the same used for the predicate device JDentalCare® implant system (K143142), the sterilization methods are the same, thus JDENTAL considered that the blister validation report validating the packaging used for dental implants is still valid.

OTHER TESTS
The devices have addressed pyrogenticity information according to FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."

7. Substantial Equivalence Discussion:

COMPARISON TABLE FOR GENERAL FEATURES

	Proposed device	Predicate device	Reference devices		
Item	JDENTALCARE® JDIcon® Implant System (K182081)	JDENTALCARE® Implant System (K143142)	ADIN-TOUAREG CloseFit™ UNP 2.75mmD (K153111)	NOBEL BIOCARE NobelActive 3.0 (K102436)	STRAUMANN DENTAL Implant System SLA (K123784)
Indication for Use	*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 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, in order to restore chewing function.* *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. When a one-*	JDENTALCARE® implant system is intended for surgical placement in the upper or lower jaw. JDentalCare® implant system is comprised of dental implant fixtures and prosthetic devices. JDentalCare® implant system 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 abutment 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, in	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 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.	The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.	Straumann Dental Implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann Dental Implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded case.

	stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.	order to restore chewing function.			

General features comparison description.

The indication for use of the JDentalCare® Implant System JDIcon® is similar to the one declared by the predicate device JDentalCare® implant system (K143142), because JDIcon® implant systems are new fixtures of dental implants manufactured by J Dental Care S.r.l.
Differences are related to the specific application intended for JDentalCare® JDIcon® Implant System 2,75 mm. For this particular indication for use, the proposed Device Family JDentalCare® JDIcon® Implant System declares the same specific use (*JDIcon® 2.75mm D Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors*) to the one declared by the reference device ADIN TOUAREG CloseFit™ UNP 2.75mmD (K153111), which propose implant fixture having the same diameter and length. Specifically, both 2.75 mm Implant fixture devices are intended for single or multiple unit applications, and for single-stage or two-stage procedures, just to replace maxillary lateral incisors and mandibular lateral and central incisors.

The indication for use of the proposed device JDentalCare® Implant System JDIcon® can also be considered equivalent to the indication for use of the other reference devices because all the reference devices are designed *to be surgically placed in upper or lower jaw or, in other words, in the bone of the mandible and/or maxillary*.
Particularly, the JDentalCare® Implant System JDIcon®, as the predicate device JDentalCare® implant system (K143142), the reference devices ADIN TOUAREG CloseFit™ UNP 2.75mmD (K153111) / NOBEL BIOCARE NobelActive 3.0 (K102436), are complete implant system, fixtures and abutments with different fixture models.

The device STRAUMANN Dental Implant System SLA cleared in K123784, has been considered as reference device because it has the same surface treatment of the proposed device.

Therefore, in terms of indications for use, the JDentalCare® Implant System JDIcon® devices can be considered substantially equivalent to the identified predicate and reference devices.
The JDentalCare® Implant System JDIcon® is compliant to the same standards which have been applied by the predicate device JDentalCare® Implant System JDIcon® (K143142).

Conclusion – General Features
In light of evidence discussed above, considering the general features of the device, the proposed JDentalCare® implant system JDIcon® may be found substantially equivalent compared to the identified predicate and reference devices.

COMPARISON TABLE FOR ENDOSSEOUS IMPLANTS FIXTURE

	Proposed device	Predicate device	Reference device
	JDIcon® Implant System (K182081))	JDENTALCARE® Implant System (K143142)	ADIN - TOUAREG CloseFit™ UNP 2.75mmD (K153111)
Indication	*Immediate or delayed load*	Immediate or delayed load	Immediate or delayed load
Placement method	*Dual or single stage surgery*	Dual or single stage surgery	Dual or single stage surgery
Materials	*Titanium Grade 5 Ø2.75 mm*	Titanium Grade 5 Ø 3,25mm	Titanium Grade 23 Ti 6AL-4V ELI
	Titanium Grade 4 Ø 3.9 / 4.3 / 5 mm	Titanium Grade 4 Ø 3.7 / 4.3 / 5 / 6 mm	
Design – Mechanical features			
Shape	*Two pieces Tapered screw Conical with Internal Hexagon*	Two pieces Tapered screw Internal Hexagon	Two pieces Tapered screw Conical-Hex connection
Thread of the body	*Double Thread Lead 1,2mm (thread space) outline: trapezoidal*	Double Thread Lead 1,2 mm (thread space) outline: trapezoidal	Triple Lead thread with 3 mm pitch
Neck features	*Collar with crestal grooves lead 0,25 mm (for Ø2,75 mm)*	Collar with Crestal grooves lead 0,3 mm	Collar with crestal grooves lead
Design – Surface features			
Body	*Sandblasting followed by acid etching*	Double Acid Etching	OsseoFix™ and anodized
Neck	*Sandblasting followed by acid etching (for fully threated version)*	N/A	OsseoFix™ and anodized
Design - Dimensions			
Diameter x Length (mm) C – Machined Collar NC – Fully treated (Not machined Collar)	NC 2.75 x 10		NC 2.75 x 10
	NC 2.75 x 11.5		NC 2.75 x 11.5
	NC 2.75 x 13		NC 2.75 x 13
	NC 2.75 x 15		NC 2.75 x 16
	-	-	
	NC 3.9 x 8	NC 3.7 x 8	
	NC 3.9 x 10	NC 3.7 x 10	
	NC 3.9 x 11.5	NC 3.7 x 11.5	
	NC 3.9 x 13	NC 3.7 x 13	
	NC 3.9 x 15	NC 3.7 x 15	
	-		
	C 3.9 x 10 (*)	NC 3.7 x 8	
	C 3.9 x 11.5 (*)	NC 3.7 x 10	
	C 3.9 x 13 (*)	NC 3.7 x 11.5	
	C 3.9 x 15 (*)	NC 3.7 x 13	
	-	-	
	NC 4.3 x 8	NC 4.3 x 8	
	NC 4.3 x 10	NC 4.3 x 10	
	NC 4.3 x 11.5	NC 4.3 x 11.5	
	NC 4.3 x 13	NC 4.3 x 13	
	NC 4.3 x 15	NC 4.3 x 15	
	-	-	

	Proposed device	Predicate device	Reference device
	JDIcon® Implant System (K182081))	JDENTALCARE® Implant System (K143142)	ADIN - TOUAREG CloseFit™ UNP 2.75mmD (K153111)
	C 4.3 x 10 (*)	NC 4.3 x 8	
	C 4.3 x 11.5 (*)	NC 4.3 x 10	
	C 4.3 x 13 (*)	NC 4.3 x 11.5	
	C 4.3 x 15 (*)	NC 4.3 x 13	
	-	-	
	NC 5.0 x 8	NC 5.0 x 8	
	NC 5.0 x 10	NC 5.0 x 10	
	NC 5.0 x 11.5	NC 5.0 x 11.5	
	NC 5.0 x 13	NC 5.0 x 13	
	NC 5.0 x 15	NC 5.0 x 15	
	-	-	
	C 5.0 x 10 (*)	NC 5.0 x 8	
	C 5.0 x 11.5 (*)	NC 5.0 x 10	
	C 5.0 x 13 (*)	NC 5.0 x 11.5	
	C 5.0 x 15 (*)	NC 5.0 x 13	
Type	Conical connection with internal hexagon	Internal Hexagon	Conical – Hex connection
Platform size / Abutment interface (mm)	Plat / Diameter 2.3 2.75 3.4 3.90 3.4 4.30 3.4 5.00	Plat / Diameter - 3.4 3.7 3.4 4.3 3.4 5.0	Plat / Diameter 2.25 2.75
kind of package	Plastic vial + blister	Plastic vial + blister	Double vial
Sterile	Yes Gamma Radiation	Yes Gamma Radiation	Yes Gamma Radiation

(*) see collar comparison description

Endosseous implant fixtures comparison description.

JDentalCare® Implant System JDIcon® and the predicate device JDentalCare® Implant System (K143142) and reference devices (K153111) are indicated for delayed or immediate loading, with the warning that for the immediate loading a good primary stability shall be achieved. JDentalCare® Implant System JDIcon®, can be used both for dual or single stage surgery, like the predicate device (K143142) and reference devices (K153111).

The materials used to manufacture the JDentalCare® Implant System JDIcon® Endosseus dental implants are Titanium Grade 4 (implant fixtures diameters 3.9 / 4.3 / 5 mm) and Titanium Grade 5 for implant fixtures diameter 2.75 mm. The predicate device uses the same materials for similar components: Titanium Grade 4 (diameters 3.7 / 4.3 / 5 / 6 mm) and Titanium Grade 5 for dental implants with the smaller diameter (3,25 mm for the predicate K143142).

Both Titanium Grade 4 (compliant to the ASTM F67) and Titanium Grade 5 (compliant to the ASTM F136) are widely recommended in biomedical applications, such as implantable components, due to their biocompatibility with human tissue. The biocompatibility of the proposed devices has been verified by means of specific tests, according to ISO 10993-1 and related standards.

Moreover, the mechanical difference between Titanium Grade 5 and titanium Grade 23 adopted by the reference devices (K153111) have been addressed and justified by means of mechanical test according to ISO standard 14801:2007.

The shape of the fixtures, the shape of the neck and the kind of thread and/or micro-thread used to manufacture the fixtures included in the JDentalCare® implant system JDIcon® are very similar to the mechanical solution adopted by the predicate devices and reference devices.

(*) Implant bodies with collar version (1.5 mm for diameters 3.9 / 4.3 / 5.0). The mechanical features for this solution can be considered the same if compared to the fully treated version having similar implantable length. Particularly, considering that the implantable section of a collar versions is equal to the total length reduced by the collar dimension (L – 1,5 mm) similar implantable length have been taken into account while comparing the predicate devices JDentalCare® (JDEvolution –K143142).

About biocompatibility, we can consider the Titanium Grade 4 and 5 property and similitude claimed for surface treatment with reference device STRAUMANN Dental Implant System SLA (K123784).

The surface treatment of the subject device JDentalCare® implant system JDIcon® is substantially equivalent to the surface of the reference device K123784.

About dimensions, the comparison table shows that dimensions are similar between the proposed device JDentalCare® implant system JDIcon® and its predicate/references devices and any remaining small differences do not impact substantial equivalence.

Particularly:
Dimensions combinations 2.75 x 10 / 11.5 / 13 are the same proposed by the reference device TOUAREG CloseFit™ 2.75mmD – (K153111). The dimension combination 2.75 x 15 results within the range of the reference device (K153111 - 2.75 x 16 mm). We believe that it can be considered structurally able to perform the expected performances, according to *"Class II Specials Control Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".*

Even if not all combinations are identical, the proposed dimensions are all within the same diameter x length range of the primary predicate and reference devices, thus can be considered substantially equivalent.

Connection system.
JDentalCare® implant system JDIcon®, similarly to the predicate device JDentalCare® implant system (JDEvolution – K143142) and the reference devices (K153111) have a connection solution with internal hexagon. Particularly, the connection system for the two-pieces JDentalCare® Implant System JDIcon® 2.75 mm implants is conical with internal Hexagon, as the reference device TOUAREG CloseFit™ 2.75mmD (K153111).

For the small implant diameter (2.75 mm) the platform size and abutment interface ratio are similar to the one proposed by the reference device (K153111).

The platform size and abutment interface for proposed diameters 3.9 / 4.3 / 5.0 mm are very similar to the ones adopted by the predicate device JDentalCare® implant system (JDEvolution – K143142) having diameters 3.7 / 4.3 and 5.0 mm.

To verify the mechanical design of the connection system JDentalCare® has performed specific mechanical tests, in compliance with ISO 14801 method. Thus, the methods of connection used by the JDentalCare® implant system JDIcon® are substantially equivalent to the connection methods used by the predicate and reference devices.

Packaging.

The JDentalCare® Implant System JDIcon® fixtures are sold in sterile condition, into a double package composed by a plastic vial inserted into a blister. Sterilization is done through gamma rays. This kind of packaging and sterilization method is exactly the same used for the predicate device JDentalCare® implant system (K143142).

The sterilization method has been and the related validation protocol and report have already been submitted to the Agency.
The packaging of the JDentalCare® Implant System JDIcon® fixtures is exactly the same of the packaging used for the predicate device JDentalCare® implant system (K143142), thus the validation of packaging and shelf life, in order to maintain the sterility condition for 5 years can be considered valid also for the JDIcon® implants.

Conclusion – Endosseous implant fixtures
In light of evidence discussed above, materials, shape, surface treatment, dimensions, connection system, packaging and sterilization method may be found substantially equivalent compared to the identified predicate and reference devices.

COMPARISON TABLE FOR ABUTMENTS FEATURES

	Proposed device		Predicate device		Reference device			
Features	JDIcon® Implant System (K182081)		JDENTALCARE® Implant System (K143142)		ADIN - TOUAREG CloseFit™ UNP 2.75mmD (K153111)		NOBEL BIOCARE NobelActive 3.0 (K102436)	
Design								
Healing abutment	Available in 3 height: 3, 5 and 7 mm Material: Titanium Grade 5		Available in 3 height: 3,5,7mm Material: Titanium Grade 5		Ref from UNP0046 to UNP0050 Ref from UNP0004 to UNP0013 Material Ti 6Al 4V ELI		Ref. models 36794-36795-36796. Available in 3 height: 3,5,7mm Material: Titanium Grade 5	
	Diameter x Height	Implant Diameter	Diameter x Height	Implant Diameter	Diameter x Height	Implant Diameter	Diameter x Height	Implant Diameter
	3.2 x 3/5/7 (mm)	2.75 (mm)	//		2.75 x 3/5/7 (mm)	2.75 (mm)	3.2 x 3/5/7 (mm)	3.00 (mm)
	4.0 x 3/5/7 (mm)	2.75 (mm)			4.0 x 3/5/7 (mm)	2.75 (mm)	3.8 x 3/5/7 (mm)	3.00 (mm)
	4.0 x 3/5/7 (mm)	3,9 (mm)	4.0 x 3/5/7 (mm)	3,7	//		//	
	4.0 x 3/5/7 (mm)	4,3/5 (mm)	4.0 x 3/5/7 (mm)	4,3/5				
	5.0 x 3/5/7 (mm)	3,9 (mm)	5.0 x 3/5/7 (mm)	3,7				
	5.0 x 3/5/7 (mm)	4,3/5 (mm)	5.0 x 3/5/7 (mm)	4,3/5				
			5.0 x 9 (mm)	3.7/4.3/5.0				
	6.0 x 3/5/7 (mm)	3.9	6.0 x 3/5/7 (mm)	3.7				
	6.0 x 3/5/7 (mm)	4.3/5.0	6.0 x 3/5/7 (mm)	4.3/5.0				
Temporary abutments	Engaging / Non-Engaging models. Material: Titanium Grade 5		Engaging / Non-Engaging models. Material: Titanium Grade 5		Engaging / Non-Engaging models. Material: Ti 6Al 4V ELI		Engaging / Non-Engaging models. Ref. model 36779 (Engaging) Material: Titanium Grade 5	
	Exagon/Diameter	Implant Diameter	Exagon/Diameter	Implant Diameter	Exagon/Diameter	Implant Diameter	Exagon	Implant Diameter
	1.8 mm Eng.	2.75	//		1.9 mm Eng.	2.75	1.5 mm Eng.	3.0
	-	-			Non engaging	2.75		
	2.65 mm Eng.	3.9	2.65 mm Eng.	3.7	//		////	
	2.65 mm Eng.	4.3 / 5.0	2.65 mm Eng.	4.3 / 5.0 / 6.0				
	3.3 mm Non Eng.	3.9	3.3 Non Eng.	3.7				
	3.3 mm Non Eng.	4.3 / 5.0	3.3 Non Eng.	4.3 / 5.0 / 6.0				

	Proposed device		Predicate device		Reference device			
Features	JDIcon® Implant System (K182081)		JDENTALCARE® Implant System (K143142)		ADIN - TOUAREG CloseFit™ UNP 2.75mmD (K153111)		NOBEL BIOCARE NobelActive 3.0 (K102436)	
GP Abutment .	Material: Titanium Grade 5 Abutment screw: included		Material: Titanium Grade 5 Abutment screw: included				Narrow profile abutments. Ref. codes 36781 – 36780 Material: Titanium Grade 5 Abutment screw: included	
	Diameter x height	Implant Diameter	Diameter x height	Implant Diameter	Diameter x height	Implant Diameter	Diameter x height	Implant Diameter
	3.2/4.0 mm x 10	2.75			//		3.2 mm x 7.0/9.0	3.0
	4.0/5.0 mm x 10.5	3.9	4.0/5.0 mm x 10.5	3.7			//	
	6.0 mm x 10.5	3.9	6.0 mm x 10.5	3.7				
	4.0/5.0 mm x 10.5	4.3/5.0	4.0/5.0 mm x 10.5	4.3/5.0				
	6.0 mm x 10.5	4.3/5.0	6.0 mm x 10.5	4.3/5.0				
Fixed Prosthesis Straight abutment	Material: Titanium Grade 5		Material: Titanium Grade 5		Collar Height 1.0–2.0–3.0 mm Straight (Ref. Code UNP0019-0011-0064) Material: Ti 6Al 4V ELI		Collar Height 1.5–3–4.5 mm Straight (Ref. Code 36782 – 36783 - 36814) Material: Titanium Grade 5	
	Dia x Collar Height	Implant Diameter	Dia x Collar Height	Implant Diameter	Dia x Collar Height	Implant Diameter	Dia x Collar Height	Implant Diameter
	//		//		4.0 x 1	2.75	4.0 x 1.5 mm	3.0
	4.0 x 2 mm	2.75			4.0 x 2	2.75	4.0 x 3.0 mm	3.0
	4.0 x 4 mm	2.75			4.0 x 3	2.75	4.0 x 4.5 mm	3.0
	4.5 x 2 mm	3.9	4.5 x 2 mm	3.7	//		//	
	4.5 x 4 mm	3.9	4.5 x 4 mm	3.7				
	4.5 x 2 mm	4.3/5	4.5 x 2 mm	4.3/5				
	4.5 x 4 mm	4.3/5	4.5 x 4 mm	4.3/5				
	5.0 x 2 mm	3.9	5.0 x 2 mm	3.7	//		//	
	5.0 x 4 mm	3.9	5.0 x 4 mm	3.7				
	5.0 x 2 mm	4.3/5	5.0 x 2 mm	4.3/5				
	5.0 x 4 mm	4.3/5	5.0 x 4 mm	4.3/5				
	6.0 x 2 mm	3.9	6.0 x 2 mm	3.7				
	6.0 x 4 mm	3.9	6.0 x 4 mm	3.7				
	6.0 x 2 mm	4.3/5	6.0 x 2 mm	4.3/5				
	6.0 x 4 mm	4.3/5	6.0 x 4 mm	4.3/5				

	Proposed device		Predicate device		Reference device	
Features	JDIcon® Implant System (K182081)		JDENTALCARE® Implant System (K143142)		ADIN - TOUAREG CloseFit™ UNP 2.75mmD (K153111)	NOBEL BIOCARE NobelActive 3.0 (K102436)
Fixed Prosthesis Anatomic Abutments	Collar height: 1.5 – 3 mm Straight Material: Titanium Grade 5		Collar height 1,5 – 3 Straight Material: Titanium Grade 5		//	//
	Dia x Collar Height x Angle	Implant Diameter	Dia x Collar Height x Angle	Implant Diameter	//	//
	5.0 x 1.5 x Straight	3.9	5.0 x 1.5 x Straight	3.7		
	5.0 x 3.0 x Straight	3.9	5.0 x 3.0 x Straight	3.7		
	5.0 x 1.5 x Straight	4.3 / 5.0	5.0 x 1.5 x Straight	4.3 / 5.0		
	5.0 x 3.0 x Straight	4.3 / 5.0	5.0 x 3.0 x Straight	4.3 / 5.0		
Fixed prosthesis Conical Abutments	Straight (Angle 0°) Material: Titanium Grade 5		Straight (Angle 0°) Material: Titanium Grade 5		//	//
	Dia x Collar Height x Angle	Implant Diameter	Dia x Collar Height x Angle	Implant Diameter	//	//
	4.8 x 1.5 / 3.0 x 0°	3.9	4.8 x 1.5 / 3.0 x 0°	3.7		
	4.8 x 1.5 / 3.0 x 0°	4.3 / 5.0	4.8 x 1.5 / 3.0 x 0°	4.3 / 5.0		
Overdenture Ball Abutments	Height: 1.5 – 3 – 5 mm Material: Titanium Grade 5		Height: 1.5 – 3 – 5 mm Material: Titanium Grade 5		Height 0.5-1.0-2.0-3.0-4.0-5.0 Material: Ti 6Al 4V ELI	//
	Collar Height	Implant Diameter	Collar Height	Implant Diameter	Collar Height / Implant Diameter	
	1.5 / 3.0 / 5.0	2.75	//		1.5 / 3.0 / 5.0 / 2.75	
	1.5 / 3.0 / 5.0	3.9	1.5 / 3.0 / 5.0	3.7	//	
	1.5 / 3.0 / 5.0	4.3 / 5.0	1.5 / 3.0 / 5.0	4.3 / 5.0		
Overdenture Emi Abutments	Height: 1.5 – 3 – 5 mm Material: Titanium Grade 5		Height: 1.5 – 3 – 5 mm Material: Titanium Grade 5		//	//
	Collar Height	Implant Diameter	Collar Height	Implant Diameter		
	1.5 / 3.0 / 5.0	3.9	1.5 / 3.0 / 5.0	3.7		
	1.5 / 3.0 / 5.0	4.3 / 5.0	1.5 / 3.0 / 5.0	4.3 / 5.0		
Materials	Titanium Grade 5		Titanium Grade 5		Titanium Alloy Ti 6Al 4V ELI (Grade 23)	Titanium Grade 5
Sterility	Non sterile		Non sterile		Sterile	Sterile

Abutments comparison description.
The abutments included in the submission are designed to allow the user to perform a complete restorative process as the abutments included in the predicate device JDentalCare® implant system (K143142) and reference devices (K153111) and (K102436).

As shown in the comparison table, the design characteristics of JDentalCare® implant system JDIcon® abutments are very similar to the design of the abutments of predicate and reference devices. They have similar material, similar connection system to the implant and similar design features of the abutments related to the predicate and the reference devices.
Remaining small differences do not impact the substantial equivalence of the device.

Considering the FDA Guidance, *"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]",* specific mechanical tests have been performed in order to confirm the substantial equivalence of the abutments.

Conclusion – Abutments
In light of evidence above, materials, shape, surface treatment, dimensions and connection system may be found substantially equivalent compared to the identified predicate and reference devices.

8. Applicable Standards:

The Family of JDentalCare® Implant System JDIcon® has been developed and tested according to the following international standards:

- ASTM F67 - Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
- ASTMF136 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications
- ISO 14801 - Dynamic fatigue test for endosseous dental implants
- ISO 11137-1 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical device
- ISO 11137-2 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ASTM F1980 - Standard Guide For Accelerated Aging of Sterile Medical Devices Packages.
- ISO 10993-1 - Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process
- ISO 10993-3 - Biological Evaluation of Medical Devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5 - Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 - Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 - Biological Evaluation of Medical Devices Part 11: Tests for systemic toxicity
- ISO 22674 - Dentistry -- Metallic materials for fixed and removable restorations and appliances

- ISO 5832-2 Implants For Surgery - Metallic Materials - Part 2: Unalloyed Titanium
- ISO 5832-3 Implants For Surgery -- Metallic Materials -- Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy

9. Conclusions

Considering technological characteristics (indication for use, material used, dimensions and features) and performance data (mechanical tests, biocompatibility tests, sterilization and shelf life), the proposed device JDentalCare® implant system JDIcon® family, may be found substantially equivalent compared to the identified primary predicate devices (K143142) and to the reference devices (K153111 - K102436 - K123784).