August 17, 2018

OsteoReady LLC
% Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22817 Ventura Blvd.
Woodland Hills, California 91364

Re: K173575
Trade/Device Name: OsteoReady® Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 12, 2018
Received: July 25, 2018

Dear Daniela Levy:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 - Indication for Use Statement

510(k) Number (if known):
K173575

Device Name:

OsteoReady® Dental Implant System

Indications for Use (*Describe*)

Indications for Use:

OsteoReady® Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. RidgeReady® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

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510(k) Summary (21 CFR 807.92)

510(k) Number K173575

1	Submission Owner	OsteoReady LLC Dr. Robert Gottlander 150 Baker Ave. Ext. Ste.110 Concord, MA 01742 USA Phone : 206-812-7727 Fax : 800-721-4907
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22815 Ventura blvd. Woodland Hills, CA 91364 Phone: 1-213-787-3027 Email: sterlingmedical2017@gmail.com
3	Prepared Date	August 16, 2018
4	Device Trade Name	OsteoReady® Dental Implant System
5	Regulation Description	Endosseous Dental Implants Abutment
6	Classification	Primary Product Code: DZE Device Name : Implant, endosseous, root-form Regulation No : 872.3640 Class : II Panel : Dental Secondary Product Code: NHA
7	Reason for the Premarket Notification Submission	: New Device
8	Identification of Legally Marketed Predicate Devices:	

OsteoReady® Dental Implant System is substantially equivalent to the following:
Primary Predicate: MIS Implants System K040807;

Reference Devices: NobelActive K142260; DENTIN Implants System K120530; MIS K163349; A.B.Dental Implants System K112440; OsteoReady ZircoSeal Abutments K151169;

in terms of intended use, indication for use, raw material, technological characteristics and performance. The predicate devices are a Class II medical device.

9 Device Description: :

OsteoReady® Dental Implant System is consist of endosseous form dental implants, internal hex implants, tapered design; cover screws, healing caps and abutment systems;

Dental Implants:

Performance implants are available as follow: Diameters 3.85, 4.2, 5.0 and 6.0mm with lengths, 7 (7mm only to 5&6 dmm), 8, 10, 11.5, 13, & 15 (15mm not for 6.0 dm);

Performance Hybrid Implants are available as follow: Diameter 3.85mm with lengths of 10, 11.5, 13 and 15mm;

RidgeReady Implants are available as follow: Diameter 3.0mm with lengths of 8.0, 10, 12, and 14mm;

Dental Abutments:

Healing Caps, Temporary Abutment, Anatomic Angulated Abutment 15, Anti-Rotation Abutment Slim / Standard, Anatomic Abutment, Angulated Abutment 15, Anti-Rotation Abutment with Collar, Ball Attachments, PEEK Temporary Abutment, O-Ring Abutments, Direct Clip Abutments, attachments for ball.

10 Indication for Use: :

OsteoReady® Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. RidgeReady® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

11 Performance Standards or Special Controls :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.

- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.

12 Substantial Equivalence :

Indication for Use Table

Candidate OsteoReady Dental Implant System	PRIMARY PREDICATE **Lance Implant**	REFERENCE DEVICE **NobelActive 3.0 Implants**	REFERENCE DEVICE **DENTIN Implant System**	REFERENCE DEVICE **A.B.Dental Devices**
K173575	K040807	K142260	K120530	K112440
OsteoReady LLC	MIS Implant Technologies Ltd	Nobel Biocare USA LLC	DENTIN Implants Technologies ltd	A.B. Dental Implants System
OsteoReady® Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. RidgeReady® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.	The MIS Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.	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. 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,	DENTIN® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage	The AB Dental Devices implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. I7 Integral implant, I5 Conical implant, P15 Temporary abutment, P12-T,L Temporary flat connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

		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 single unit restorations only.	Implants: PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.	

Discussion

OsteoReady shares the same indication for use as its primary predicate. The only difference is related to statement of RidgeReady® 3.0 implants which are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. This statement is similar to the reference devices NobelActive K142260 and DENTIN K120530 since these reference devices also introduce the 3.0ø implants, whereas the primary predicate doesn't introduce the 3.0ø implants . Therefore, OsteoReady doesn't introduce any new safety or efficacy issues.

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Dental Implants System

CHARACTERISTIC	Candidate No.1 Performance Implants	PRIMARY PREDICATE Lance Implant
510k	K173575	K040807
Company Name	OsteoReady LLC	MIS Implant Technologies Ltd
Device Design	Threaded, root form endosseous implants	Threaded, root form endosseous implants
Classification	Class 2 872.3640 P.Code DZE	Class 2 872.3640 P.Code DZE
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI
Diameters mmd	3.85, 4.2, , 5, 6	3.75, 4.2, 5
Lengths mml	7 [only to 5 & 6 mmd] 8, 10, 11.5, 13 15 [Not for 6.0 mmd]	10, 11.5,13, 16
Connection Type	Internal Hex	Internal Hex
Implant Body Contour	Tapered, Self Tapping	Tapered, Self Tapping
Coating / Surface	Sand Blast & Acid Etched	Sand Blast & Acid Etched
Anatomical Site	Oral Cavity	Oral Cavity
Principle of operation	Conventional procedure	Conventional procedure
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

CHARACTERISTIC	Candidate No.2 Performance Hybrid Implants	PRIMARY PREDICATE SEVEN Implants
510k	K173575	K040807
Company Name	OsteoReady LLC	MIS Implant Technologies Ltd
Device Design	Threaded, root form endosseous implants	Threaded, root form endosseous implants
Classification	Class 2 872.3640 P.Code DZE	Class 2 872.3640 P.Code DZE
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI
Diameters mmd	3.85	3.75, 4.2, 5, 6
Lengths mml	10, 11.5, 13, 15	8, 10, 11.5, 13, 16 (N/A for 6mmd)
Connection Type	Internal Hex	Internal Hex
Implant Body Contour	Tapered, Self Tapping	Tapered, Self Tapping
Coating / Surface	Sand Blast & Acid Etched	Sand Blast & Acid Etched
Anatomical Site	Oral Cavity	Oral Cavity

Principle of operation	Conventional procedure	
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

CHARACTERISTIC	Candidate No.3 RidgeReady Implants	REFERENCE DEVICE NobelActive 3.0 Implants
510k	K173575	K142260
Company Name	OsteoReady LLC	Nobel Biocare USA LLC
Device Design	Threaded, root form endosseous implants	Threaded, root form endosseous implants
Classification	Class 2 872.3640 P.Code DZE	Class 2 872.3640 P.Code DZE
Material	GR-5 Titanium Ti-6Al-4V EL	GR-5 Titanium Ti-6Al-4V ELI
Diameters dmm	3.0	3.0, 3.5, 4.3, 5.0, 5.5
Lengths lmm	8, 10, 12, 14	7, 8.5, 10, 11.5, 13, 15, 18
Connection Type	Internal Hex	Internal Hex
Implant Body Contour	Tapered, Self Tapping	Tapered, Self Tapping
Surface	Sand Blast & Acid Etched	TiUnite
Anatomical Site	Oral Cavity	Oral Cavity
Principle of operation	Conventional procedure	Conventional procedure
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

Dental Abutments System

	Candidate	***Primary Predicate***	***Reference Device***
Company / 510k	***OsteoReady LLC K173575***		***DENTIN 510K 120530***
Product Name	***Healing Caps***		***Healing Caps***
Dimensions mm	Slim - Length 1,2,3,4,5,6,7 Standard - Length 1,2,3,4,5,6,7 Wide - Length 2,3,4,5,6,7 Narrow Diameter 3.0 - Height 1,3,5		Slim - Length 1,2,3,4,5,6,7 Standard - Length 1,2,3,4,5,6,7 Wide - Length 2,3,4,5,6,7 Narrow Diameter 3.0 - Height 1,3,5
Material	Titanium alloy Ti-6Al-4V-ELI.		Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex		Internal Hex
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	***DENTIN 510K 120530***

Product Name	***Anatomic Angulated Titanium Abutment***	***Esthetic Angulated Abutment***	***Anatomic Angulated Titanium Abutment***
Dimensions mm	Height 1,2,3,4 - Angle 15	Height 1,2,3 - Angle 15	Height 1,2,3,4 - Angle 15
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	***DENTIN 510K 120530***
Product Name	***Anti-Rotation Abutment Slim***	***Cemented Abutment***	***Slim Titanium Abutment***
Dimensions mm	Diameter 3.8 Length 5, 7, 9, 12 mm	Diameter 3.75 Length 8.5, 11	Diameter 3.8 Length 5, 7, 9, 12, 15
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	***DENTIN 510K 120530***
Product Name	***Anti-Rotation Abutment***	***Cemented Abutment***	***Titanium Abutment***
Dimensions mm	Diameter 4.5 Length 5, 7, 9, 12	Diameter 4.7 Length 11	Diameter 4.5 Length 7, 9, 12
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	***DENTIN 510K 120530***
Product Name	***Anatomic Titanium Abutment***	***Anatomic transgingival Abutment***	***Anatomic Titanium Abutment***
Dimensions mm	Height 1,2,3,4	Height 1,2,3,4	Height 1,2,3,4
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Company / 510k	***OsteoReady LLC***	***MIS K040807***	***DENTIN 510K 120530***
Product Name	***Angulated Titanium Abutment***	***Angulated Cement Abutment***	***Angulated Titanium Abutment***
Dimensions mm	Length 9 - Angle 15	Length 9,11 - Angle 15	Length 9,12 - Angle 15
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
	Candidate	***Primary Predicate***	***Reference Device***
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	***DENTIN 510K 120530***
Product Name	***Anti-Rotation Abutment with Collar***	***Straight Cement Abutment***	***Straight Titanium Abutment***
Dimensions mm	Diameter 4.5 Length 1,2,3,4	Diameter NP, RP, WP Length 1,2,3,4	Diameter 4.5 Length 1,2,3,4

Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Product Name	***Ball Attachment***	***Ball Attachment***	***Ball Attachment***
Dimensions mm	Height 0.5,1,2,3,4,5,6	Height 1,2,3,4,5	Height 0.5,1,2,3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Related Components	Metal Caps, Silicon Caps	Metal Caps, Silicon Caps	Metal Caps, Silicon Caps
Company / 510k	***OsteoReady LLC K173575***	***MIS K163349***	***DENTIN 510K 120530***
Product Name	***PEEK Temporary Abutment***	***Temporary plastic abutment***	**Straight curve minor - *PEEK***
Dimensions mm	Height 1,2,3,	NP,RP Height 1,2,3	Height 1,2,3,
Material	PEEK	PEEK	PEEK
Connection	Internal Hex	Internal Hex, conical	Internal Hex
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	**A.B.Dental Devices *K112440***
Product Name	**O-Ring Abutments**	***Ball Attachment***	**Straight Adaptor P16**
Dimensions mm	Diameter 3.0 mm	Diameter NP Height 1,2,3 mm	Diameter 3.0 mm Height 1,2,3,4 mm
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
Company / 510k	***OsteoReady LLC K173575***		**A.B.Dental Devices *K112440***
Product Name	***Direct Clip Abutments***		**Straight Adaptor P16**
Dimensions mm	Diameter 3.0 mm, Height 1,3,5		Diameter 3.0 mm Height 1,2,3,4 mm
Material	Titanium alloy Ti-6Al-4V-ELI.		Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex		Internal Hex
	Candidate	***Primary Predicate***	***Reference Device***
Company / 510k	***OsteoReady LLC K173575***	***MIS K040807***	
Product Name	***Straight Abutments***	**Transgingival Abutment, NP**	
Dimensions mm	Diameter 3.0 mm, Height 0.5,2.5,4.5	Diameter NP, Height 1,2,3,4	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal Hex	Internal Hex	

13 Summary of Equivalence:

OsteoReady® Dental Implant System: Performance Implants & Performance Hybrid Implants share similarity to MIS Implants System K040807; RidgeReady Implants share similarity to NobelActive K142260; in terms of intended use, indication for use, technological characteristics, design, raw material and performance. The minor difference is regarding to OsteoReady diameter size which is wider, however it doesn't introduce any new safety or efficacy issues. OsteoReady Dental Implant system is made of Titanium alloy Ti-6Al-4V-ELI as in similar to its primary predicate.

OsteoReady® Dental Abutment System shares similarity to MIS Implants System K040807, K163349; DENTIN Implants System K120530; A.B.Dental Implants System K112440; in terms of intended use, indication for use, technological characteristics, design, raw material and performance.

The minor difference is regarding to measurements related few abutments types, however it doesn't introduce any new safety or efficacy issues since similar measurements are already exist in the market.

As demonstrated by the substantial equivalent table, the minor differences of OsteoReady LLc vs. its predicate and reference devices raise no new safety or/and effectiveness issues and therefore OsteoReady® Dental Implant System is considered to be substantial equivalent to its predicate and reference devices.

14 Non Clinical Performance:

Sterilization Validation Test was carried out with accordance to ISO 11137 in order to demonstrate substantial equivalence of OsteoReady® Dental Implants. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

LAL/endotoxin testing was carried out with accordance to USP 161 and USP 85. Test results have met the criteria.

OsteoReady will not market its Dental Implant System as “non-pyrogenic”.

Shelf Life Test was carried out with accordance to ASTM F-1980 in order to demonstrate substantial equivalence of OsteoReady® Dental Implants of 5 years shelf life.

Steam Sterilization Test was carried out with accordance to ISO 17665 in order to demonstrate substantial equivalence of OsteoReady® Dental Abutments - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Packaging validation test was carried out with accordance to ASTM D4169 in order to validate the safety of the device and packaging during transportation test results were meet the criteria.

Biocompatibility - OsteoReady uses the same raw material as was previously cleared under 510k K151169 titanium alloy Ti6Al4V Eli and uses the same conventional manufacturing process. Cytotoxicity testing was conducted with accordance to ISO 10993-5 to the used raw materials: Titanium alloy and for PEEK Abutments, in order to demonstrate that the manufacturing process did not change the biocompatibility profile. Irritation testing and Sensitization testing were conducted with accordance to ISO 10993-10, all test results met the criteria.

Fatigue test was carried out with accordance to ISO 14801 in order to verify the mechanical connection strength of implant/abutment, results have demonstrated the high performance with the use of OsteoReady® Dental Implants / Abutments.

Surface Test was carried out to ensure the cleanness of the implant surface, surface results were met OsteoReady requirements.

Risk Assessment was carried out with accordance to ISO 14971 and has demonstrated no new safety and/or effectiveness issues.

15 Conclusion:

As verified by substantial equivalence, risk assessment and bench testing OsteoReady® Dental Implant System shares similarity to its predicated devices in terms of intended use, indication for use, raw material, technological characteristics and performance. Therefore, OsteoReady® Dental Implant system is considered to be substantially equivalent to its predicate and reference devices.