UNIdental Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

October 25, 2023

Re: K221315
Trade/Device Name: UNIdental Symphony Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 29, 2023
Received: October 2, 2023

Dear Priscilla Chung:

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director

DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K221315

Device Name

UNIdental Symphony Implant System

Indications for Use *(Describe)*

The UNIdental Symphony Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The UNIdental Symphony Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
(K221315)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 10/19/2023

1. Submitter

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: UNIdental Symphony Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Classification regulation: 21CFR 872.3640

4. Predicate Device:

- **Primary Predicate Device:**
  SuperLine by Dentium Co., Ltd. (K160965)

- **Reference Predicate Device:**
  ITI Dental Implant System by Straumann (K031055)
  Straumann TLX Implant System by Straumann USA, LLC (K200586)
  SuperLine by Dentium Co., Ltd. (K213599)
  DentiumImplantium® &SuperLine® Prosthetics by Dentium Co., Ltd. (K172640)

Multi-unit Abutment Plus by NOBEL BIOCARE AB (K161416)
IMPLANTIUM ABUTMENTS by DENTIUM, INC. (K052823)

5. Description:

The UNIdental Symphony Implant System is a dental implant system made of Titanium 6AL 4V ELI alloy and CP Ti Grade 4 intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implants may be used to replace one or more missing teeth. The systems are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.
Symphony 1 Fixture is Bone level, and Symphony 2 Fixture is Tissue level.

Symphony 1 Fixture is a taper shape that gradually decreases the outer diameter of the lower part from the upper part.
And It is a taper shape that gradually decreases the outer diameter of the lower part from the upper part. It is a structure that can perform a tapping function at the same time without a separate tap. It couples up with the abutment and its hexagon shape.

Symphony 2 Fixture is a structure with a round shape at the end. It couples up with the abutment and its octagon shape. The area that touches the patient's gums is pure titanium surface.

Implant Diameter	Symphony 1 Fixture	3.6, 4.0, 4.5, 5.0, 5.8mm
	Symphony 2 Fixture	3.3, 4.1, 4.8mm
Implant Length	Symphony 1 Fixture	7.0, 8.0, 10, 11.6, 12, 14mm
	Symphony 2 Fixture	9.35, 10.35, 12.35, 14.35, 15.35, 16.35, 17.35mm

The upper structure of the abutments support prosthetics such as artificial teeth to restore patient's total mouth function.

Type		Description	Raw Material	Diameter	Length
Healing Abutment	Symphony 1	The healing abutments provide the framework forsoft tissue healing and stability, which can achieve the formation of anideal emergence profile, prevent soft tissuefrom overgrowing over the implant fixture, and minimize the possibility of a second surgery.	Ti-6Al-4V ELI	4.1, 4.5, 5.0, 5.5, 6.5, 7.5, 8.5, 9.5mm	9.5, 11, 12.5, 14.5mm
	Symphony 2		Ti-6Al-4V ELI	5.5, 7.2mm	6.5,7.5, 9, 10.5, 12.5mm
Straight Abutment	Symphony 1 (Dual Abutment)	It is a general straight type superstructure. The dual abutment has the shape of an inner crown and is an abutment fixed with cement.	Ti-6Al-4V ELI	4.5, 5.5, 6.5mm	8.2, 9.2, 9.7, 10.7, 11.2, 11.7, 12.2, 12.7, 13.2, 13.7, 14.2,

		The cemented abutment has the shape of an innercrown and is an abutment that fixes the prosthesis with dental cement, and the fixture and connection part are hex.			15.2mm
	Symphony 2 (Cemented Abutment)		Ti-6Al-4V ELI	3.5, 3.55, 4.3mm	6.7, 8.2, 8.4mm
Angled Abutment	Symphony 1	It is used in case of the slope of the prosthesis where the upper part is not applicable. TiN coating has been applied to some items to prevent the metal color from appearing black on the gums. Angled Abutment combined with the Symphony 2 fixture has A type and B type, and the only difference between the two types is the direction when fastening. The allowed angulations are 15° and 25°.	Ti-6Al-4V ELI (TiN Coating)	4.5, 5.5mm	12.76, 12.89, 13.01, 13.30, 13.79, 13.89, 14.01, 14.30, 14.79, 14.89, 15.01, 15.30mm
	Symphony 2		Ti-6Al-4V ELI	3.5, 4.3mm	5.5, 6.5mm
Multi-unit Straight Abutment		This product is intended to be used by edentulous patients in the Overdenture case.	Ti-6Al-4V ELI	4.8mm	8.2, 9.2, 9.3, 10.3, 11.3, 12.3mm

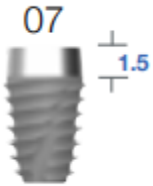
6. Indication for use:

The UNIdental Symphony Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The UNIdental Symphony Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

7. Basis for Substantial Equivalence

7.1 Fixture

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Device Name	UNIdental Symphony Implant System	SuperLine	ITI Dental Implant System	Straumann TLX ImplantSystem	SuperLine
510(k) #	K221315	K160965	K031055	K200586	K213599
Product Code	DZE, NHA	DZE	DZE	DZE, NHA	DZE
Manufacturer	UNIdentalCo.,Ltd	DENTIUM CO., LTD.	Straumann	Straumann USA, LLC (on behalf of Institut Straumann AG)	DENTIUM CO., LTD.
Indications for Use	The UNIdental Symphony Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The UNIdental Symphony Implant System is for single	SuperLine 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. SuperLine is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	ITI implants are intended for surgical placement in maxillary and/or mandibular arches to provide support for prosthetic in edentulous or partially edentulous patients. The ITI Dental Implants are for single-stage or two-stage surgical procedures.	Straumann TLX Implantsare suitable for endostealimplantation in the upperand lower jaws and forthe functional andesthetic oral rehabilitationof edentulous andpartiallyedentulou spatients. TLX Implantscan be placed withimmediate function onsingle-tooth and multi-unitrestorations when goodprimary stability isachieved and withappropriateocclus alloading to restorechewing function.	SuperLine@ implants are 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. SuperLine@ implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length

	and two stage surgical procedures. It is intended for delayed loading.				Theprosthetic restorations areconnected to the implantsthroughtheco rrespondingabutmentc omponents.	implants are indicated for delayed loading.
Implant Design	Symphony 1Fixture  Symphony 2 Fixture 		SuperLine Fixture 	Collar Type 	Straumann® TLXSP Implant 	SuperLine FXSxxxx Serie 
Implant Diameter	Symphony 1Fixture	3.6 – 7.0mm	3.6 – 7.0 mm			3.6/3.6; 4.0/4.0; 4.5/4.5; 5.0/5.0; 5.0/6.0; 5.8/7.0 mm
	Symphony 2Fixture	3.3– 4.8mm	-	3.3 – 5.37 mm	Ø3.75, 4.0, 4.5, 5.0, 5.5,and 6.5 mm	
Implant Length	Symphony 1Fixture	7.0 – 14.0mm	8.0 – 14.0 mm			Each in 7 mm length only
	Symphony 2Fixture	9.35- 17.35mm	-	8.0 – 16.0 mm	Ø3.75, 4.0, 4.5, 5.0 mm:6, 8, 10, 12, 14, 16 and18 mm Ø5.5 and 6.5 mm:6, 8, 10, 12 mm	
Implant Material	Fixture :Titanium Grade 4 ASTM F 67		Ti-6Al-4V ELI ASTM F136	Ti-6Al-4V ELI ASTM F136	Titanium-13 Zirconium alloy (Roxolid®)	All implants: unalloyed titanium, ASTM F67
Implant Coating	Non-coated		Non-coated	Non-coated	Non-coated	Non-coated

Surface Treatment	SLA Treatment	RBM(Calcium-Phosphate Media)	RBM(Calcium-Phosphate Media)	Hydrophilic SLAactive®	All implants: S.L.A., Al2O3 blasted and acid etched
Implant Surface Finish	Aluminum oxide >99% Sodium oxide <0.6% Iron (III) oxide < 0.2% Silicon dioxide < 0.1%	Calcium Phosphate : Ha: >65% Beta-TCP :<25% Alpha-TCF :<5% TTCP: <5% Other CaP :<5%	Calcium Phosphate : Ha: > 65% Beta-TCP :<25% Alpha-TCF :<5% TTCP: <5% Other CaP :<5%	-	-
Sterilization	Gamma Sterilization	Radiation sterilization	Radiation sterilization	Radiation sterilization	Gamma Sterilization

Substantial Equivalence Discussion

The subject device is substantially equivalent to to SuperLine (K160965) by Dentium Co., Ltd.
They have the same indications for use and uses the same materials. The wording of the indications for use statement might be different but that of the subject device does not introduce the new indications. It is written to elaborate on the indications more clearly.
The design is very similar, yet they may have some minor differences in design which does not raise a question in safety or performance. We have conducted a fatigue test and the results support that the subject device is substantially equivalent to the to the predicate device.
We identified references devices which compass the size range of the subject device.

7.2. Abutments

	Subject Device		Predicate Device
Device Name:	UNIdental Symphony Implant System		Dentium Implantium® & SuperLine® Prosthetics
510(k) #	K221315		K172640
Manufacturer	UNIdental Co.,Ltd.		Dentium Co., Ltd.
Product Code	DZE, NHA		NHA
Healing Abutments			
Design	Symphony 1 	Symphony 2 	
Abutment Materials	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Intended Use	To help the soft tissue of gum naturally formed	To help the soft tissue of gum naturally formed	To help the soft tissue of gum naturally formed.
Diameter	4.1~9.5mm	5.5~7.2mm	4.0~9.5mm
post heights	2.0~7.0mm		2.0~7.0mm
gingival collar heights	2~4mm		2~4mm
Surface Treatment	No	No	No
Sterilization	Steam Sterilization by user	Steam Sterilization by user	Steam Sterilization by user
Angled Abutment			
Design & Size Range	Symphony 1  Angle : 15, 25 (Internal hex)	Symphony 2  Angle : 15, 20 (Internal octa)	 Angle : 15, 25
Abutment Materials	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Intended Use	Structure of abutment lift the prosthesis	Structure of abutment Lift the prosthesis	Structure of abutment Lift the prosthesis
Diameter	4.5~5.5mm	3.5~4.3mm	4.5~5.5mm
gingival collar heights	1.5~3.5mm		1.5~3.5mm
angulations	Angle : 15, 25	Angle : 15, 20	Angle : 15, 25
Surface Treatment	TiN coating – Gold color (Partly)	No	No
Sterilization	Steam Sterilization by user	Steam Sterilization by user	Steam Sterilization by user

Dual Abutment			
Design & Size Range	 Dual Abutment (Internal hex)	-	
Abutment Materials	Ti 6Al 4V ELI, Gr.23	-	CP Ti Gr.4
Intended Use	Cement retained restoration	-	Cement retained restoration
Diameter	4.5~6.5mm	-	4.5~6.5mm
gingival collar heights	1.0~5.5mm	-	1.0~5.5mm
Surface Treatment	TiN coating – Gold color (Partly)	-	TiN coating – Gold color (Partly)
Sterilization	Steam Sterilization by user	-	Steam Sterilization by user

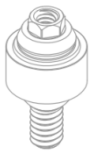
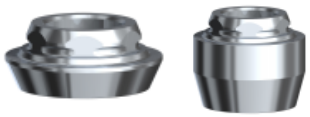
Substantial Equivalence Discussion

The subject device is substantially equivalent to SuperLine (K160965) by Dentium Co., Ltd.
They have the same indications for use and uses the same materials. The design is very similar, yet they may have some minor differences in design and dimension which does not raise a question in safety or performance. We have conducted a fatigue test and the results support that the subject device is substantially equivalent to the predicate device.

	Subject Device	**Predicate Device**
Device Name:	UNIdental Symphony Implant System	Straumann TLX ImplantSystem
510(k) #	K221315	K200586
Manufacturer	UNIdentalCo.,Ltd	DZE, NHA
Product Code	DZE, NHA	Straumann USA, LLC (on behalf of Institut Straumann AG)
Design & Size Range	 Cemented Abutment (Internal screw retained)	
Abutment Materials	Ti 6Al 4V ELI, Gr.23	Titanium alloy
Intended Use	Cement retained restoration	Cement retained restoration
Diameter	3.55~4.3mm	3.5~5mm
post heights	5.5mm	5.7mm, 6mm
angulations	Angle : 0	Angle : 0, 15
Surface Treatment	No	No
Sterilization	Steam Sterilization by user	Steam Sterilization by user

The subject device is substantially equivalent to to Straumann TLX ImplantSystem (K200586) by Straumann USA.
They have the same indications for use and uses the same materials. The design is very similar, yet they may have some minor differences in design which does not raise a question in safety or performance.

- Multi-unit Straight Abutment

	Subject Device		Predicate Device
Device Name:	UNIdental Symphony Implant System		Multi-unit Abutment Plus
510(k) #	K221315		K161416
Manufacturer	UNIdentalCo.,Ltd		NOBEL BIOCARE AB
Product Code	DZE, NHA		NHA
Design & Size Range	Symphony 1	Symphony 2	
			
Abutment Materials	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Titanium vanadium alloy
Intended Use	Structure of abutment lift the prosthesis	Structure of abutment lift the prosthesis	Structure of abutment lift the prosthesis
Diameter	4.8mm	4.8mm	4.8mm
gingival collar heights	1.0~5.0mm	1.0~5.0mm	1.5~4.5mm
angulations	Angle : 0	Angle : 0	Angle : 0, 17, 30
Surface Treatment	No	No	No
Sterilization	Steam Sterilization by user	Steam Sterilization by user	Steam Sterilization by user

Substantial Equivalence Discussion

The subject device is substantially equivalent to Multi-unit Abutment Plus (K161416) by NOBEL BIOCARE AB.
They have the same indications for use and uses the same materials. The design is very similar, yet they may have some minor differences in design which does not raise a question in safety or performance.

7. 3. Screws

	Subject Device		Predicate Device
510(K) Number	UNIdental Symphony Implant System		IMPLANTIUM ABUTMENTS
Device Name	K221315		K052823
Manufacturer	DZE, NHA		DENTIUM, INC.
Product Code	UNIdental Co.,Ltd.		NHA
Cover Screw			
Design	Symphony 1	Symphony 2	
			
Intended Use	To provide sealing effect for fixture	To provide sealing effect for fixture	To provide sealing effect for fixture

Diameter	3.6~6.0mm		3.8~5.8mm
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	No	No	Anodizing coloring(Entire Body)
Sterile	Steam Sterilization by user	Steam Sterilization by user	Radiation sterilization
Abutment Screw			
Design	Symphony 1	Symphony 2	
			
Intended Use	To connect the abutment to the fixture	To connect the abutment to the fixture	To connect the abutment to the fixture
Diameter	2.0~2.4mm		2.3mm
Material Composition	Ti-6Al-4V ELI ASTM F136	Ti-6Al-4V ELI ASTM F136	Ti-6Al-4V ELI ASTM F136
Surface Treatment	No	No	No
Sterile	Steam Sterilization by user	Steam Sterilization by user	Steam Sterilization by user

Substantial Equivalence Discussion

The subject device is substantially equivalent to toSuperLine (K160965) by Dentium Co., Ltd. They have the same indications for use and uses the same materials. The design is very similar, yet they may have some minor differences in design which does not raise a question in safety or performance. We have conducted a fatigue test and the results support that the subject device is substantially equivalent to the predicate device.

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization.
- Shelf-life testing has been performed in according with ASTM F1980, ISO 11607, ASTM F88, ASTM F1140, ASTM F1929, ASTM F2096 and ISO 11737-2.
- SEM (Scanning Electron Microscope) and EDS(Energy-dispersive X-ray spectroscopy) were performed to evaluate the fixture surface characteristics after SLA treatment.
- Biocompatibility Tests were performed in accordance with ISO 10993-3, 5, 6, 10, and 11.
- Compressive load and fatigue tests in accordance with ISO 14801
- Bacterial Endotoxin Levels (LAL) in accordance with USP 85
- MRI Safety
  A non-clinical worst-case MRI review was conducted to evaluate the UNIdental

Symphony Implant System in an MRI environment. Various dental journals were utilized to ensure its stability, and scientific evidence from literature was considered, such as the study by Yong-Ha Kim, Manki Choi, and Jae-Won Kim titled 'Are titanium implants actually safe for magnetic resonance imaging examinations?' (Arch Plast Surg 2019;46:96-97). The study concluded that titanium, being a paramagnetic material, is not affected by the magnetic field of MRI. The risk of implant-based complications is very low, and MRI can be safely used in patients with implants. Based on this paper, the stability of the raw material of the UNIdental Symphony Implant System in an MRI environment was confirmed.

In the study conducted by Woods, Terry O., Jana G. Delfino, and Sunder Rajan titled 'Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices' (Journal of Testing and Evaluation 49.2 (2019): 783-795), Titanium Grade 4 was evaluated using magnetic induction displacement force (ASTM F2052), magnetic induction torque (ASTM F2213), RF induction heating (ASTM F2182), and image artifact (ASTM F2119) tests by T. O. Woods et al. Based on this research, we have addressed parameters per FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the UNIdental Symphony Implant System has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate similar design,
* incorporate the same material and the sterilization method

Based on the similarities, we conclude that the UNIdental Symphony Implant System is substantially equivalent to the predicate devices.