DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 20, 2016

Implants Microdent System S.L
Mr. Jordi Clapés Donadeu
Quality Director
C/ Carles Buigas, I-Can Magre
Santa Eulalia de Roncana, Barcelona 08187
SPAIN

Re: K153650
Trade/Device Name: Microdent Ektos Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 11, 2016
Received: April 18, 2016

Dear Mr. Donadeu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153650

Device Name
Microdent Ektos Implant System

Indications for Use *(Describe)*
Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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.
Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla and 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 C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (21 CFR 807.92)

This 510(k) summary is submitted in accordance with the requirement of 21 CFR 807.92

The assigned 510(k) number is: K153650

Premarket Notification [510(k)] Summary

A. General Information

Submitter's Name:	Implant Microdent Systems
Address:	C/ Carles Buigas, 1 – Can Magre Sta Eulalia de Ronçana E-08187 Barcelona, Catalonia Spain
Telephone:	+34-902-402-420
Fax Number:	+34-94-844-7893
Contact Person:	Jordi Clapes Donadeu
Date Prepared:	May 9th, 2016

B. Device

Trade Name:	Microdent Ektos Implant System
Classification Name:	Endosseous Dental Implants
Product Code:	DZE and NHA (DZE is considered the primary product code)
Class:	II
Regulation Number:	21 CFR 872.3640

C. Identification of Legally Marketed Predicate Device

Legacy System Dental Implants – K073033 (primary predicate)
Microdent Genius Implant System – K141188 (reference predicate)
Legacy Abutment System – K060063 (reference predicate)

D. Description of the Device

Microdent Ektos Implant System is comprised of dental implants and prosthetic components. Microdent Ektos dental implants are internal connection endosseous implants machined in titanium that can be used with deferred load or immediate load techniques. The implant is designed to be inserted at crestal level. Microdent Ektos Implant is recommended to be placed at crestal bone level.

The implant has an internal hexagonal connection.

Microdent Ektos Implants are provided with blasted surface.

The implants are supplied sterile and the abutments are provided non-sterile.

- Implants are provided in the following diameters and length.

Ø platform	Ø core	Length	Reference
3.50	3.70	8	EK3708CP
		10	EK3710CP
		12	EK3712CP
		14	EK3714CP
		16	EK3716CP
		18	EK3718CP
3.50	4.20	8	EK4208CP
		10	EK4210CP
		12	EK4212CP
		14	EK4214CP
		16	EK4216CP
		18	EK4218CP
4.50	4.80	8	EK4808CP
		10	EK4810CP
		12	EK4812CP
		14	EK4814CP
		16	EK4816CP
		18	EK4818CP
5.70	5.80	8	EK5808CP
		10	EK5810CP
		12	EK5812CP
		14	EK5814CP
		16	EK5816CP

- The system also contains Microdent Ektos abutments made of Ti-6AL 4-V-ELI alloy as follows:

The abutments Conical, Multi-function (supplied with the implant) and Mini Capitel are used for cemented and screw-retained restorations.

Conical abutment with flap as indicated in the following table:

EKPCCP3501H	Microdent Ektos hex. Conical with flap abutment	Plat. Ø 3.50 Height 1, 3 and 5 mm
EKPCCP4501H	Microdent Ektos hex. Conical with flap abutment	Plat. Ø 4.50 Height 1, 3 and 5 mm
EKPCCP5701H	Microdent Ektos hex. Conical with flap abutment	Plat. Ø 5.70 Height 1 mm
EKPCCP3501R	Microdent Ektos Circular Conical with flap abutment	Plat. Ø 3.50 Height 1, 3 and 5 mm
EKNPCCP4501R	Microdent Ektos Circular Conical with flap abutment	Plat. Ø 4.50 Height 1, 3 and 5 mm
EKPCCP5701R	Microdent Ektos Circular Conical with flap abutment	Plat. Ø 5.70 Height 1 mm

Conical abutment without flap as indicated in the following table:

EKPCSP3500H	Microdent Ektos Hex. Conical without flap abutment	Plat. Ø 3.50 Height 0 to 5 mm
EKPCSP4500H	Microdent Ektos Hex. Conical without flap abutment	Plat. Ø 4.50 Height 0 to 5 mm
EKPCSP5700H	Microdent Ektos Hex. Conical without flap abutment	Plat. Ø 5.70 Height 0 and 1 mm
EKPCSP3500R	Microdent Ektos Circular Conical without flap abutment	Plat. Ø 3.50 Height 0 to 5 mm
EKPCSP4500R	Microdent Ektos Circular Conical without flap abutment	Plat. Ø 4.50 Height 0 to 5 mm
EKPCSP5700R	Microdent Ektos Circular Conical without flap abutment	Plat. Ø 5.70 Height 0 and 1 mm

Immediate loading conical abutments as indicated in the following table:

EKPCI3500H	Microdent Ektos hex. immediate loading conical abutment	Plat. Ø 3.50 Height 0 mm
EKPC4500H	Microdent Ektos hex. immediate loading conical abutment	Plat. Ø 4.50 Height 0 mm
EKPCI5700H	Microdent Ektos hex. immediate loading conical abutment	Plat. Ø 5.70 Height 0 mm
EKPCI3500R	Microdent Ektos Circular immediate loading conical abutment	Plat. Ø 3.50 Height 0 mm
EKPC4500R	Microdent Ektos Circular immediate loading conical abutment	Plat. Ø 4.50 Height 0 mm
EKPCI5700R	Microdent Ektos Circular immediate loading conical abutment	Plat. Ø 5.70 Height 0 mm

Mini Capitel abutment as indicated in the following table:

EKCAPN3501R	Microdent Ektos Circular Mini Capitel Abutment	Plat. Ø 3.50 Height 1 to 4 mm
EKCAPN4501R	Microdent Ektos Circular Mini Capitel Abutment	Plat. Ø 4.50 Height 1 to 4 mm
EKCAPN5701R	Microdent Ektos Circular Mini Capitel Abutment	Plat. Ø 5.70 Height 1 to 2 mm
UTSNPC4X	Microdent Ektos Mini Capitel cementable coping	Ø 4.80
UTSNPC51	Microdent Ektos Mini Capitel cementable coping	Ø 5.60
UTSNCP4X	Microdent Ektos Mini Capitel Protective Cap	Ø 4.80
UTSNCP51	Microdent Ektos Mini Capitel Protective Cap	Ø 5.60

- The following Cover Screws are provided to protect the inner configuration of the implant and are supplied sterile with the implant.

EKTC35	Microdent Ektos cover screw	Plat. Ø 3.50
EKTC45	Microdent Ektos cover screw	Plat. Ø 4.50
EKTC57	Microdent Ektos cover screw	Plat. Ø 5.70

- Healing abutment to shape the soft tissue during the healing phase as indicated in the following table:

EKPR3502	Microdent Ektos Healing abutment	Ø 4.50 Height 2 to 5 mm
EKPR4502	Microdent Ektos Healing abutment	Ø 6.50 Height 2 mm
EKPR5702	Microdent Ektos Healing abutment	Ø 5.50 Height 1 to 6 mm
EKPCR3502	Microdent Ektos Healing abutment	Ø 3.50 Height 2 to 5 mm
EKPCR4502	Microdent Ektos Healing abutment	Ø 4.50 Height 2 to 5 mm
EKPCR5702	Microdent Ektos Healing abutment	Ø 5.70 Height 2 mm

- The Retention Screws are used for securing the abutments to the implant.

- Overdenture retention consists of a titanium alloy socket that attached to a threaded post for use with titanium endosseous implants having an internal threaded socket. Both devices have a plastic component that has a shape on one and that mate into the titanium socket, while the other end with metal cap is attached to the denture.

EKEOSS3500	Microdent Ektos Osscilia retention abutment	Ø 3.50 Height 0 to 4 mm
EKEOSS4500	Microdent Ektos Osscilia retention abutment	Ø 4.50 Height 0 to 4 mm
EKEOSS5700	Microdent Ektos Osscilia	Ø 5.70

	retention abutment	Height 0 to 1 mm
CSUTGOSS	Metal cap with soft, middle and strong Osscilia retainer.	Titanium grade 5 +POM

All abutments include appropriate features and dimensions to mate with Microdent Ektos implants. No compatibility with other implant systems is claimed.

E. Intended Use

Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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.
Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla and mandible.

F. Summary of Testing and Comparison to the Predicate Device

The devices are designed and manufactured in accordance with the following standards:

ISO 5832-2:1999 Implants for surgery - Metallic materials - Part 2: Unalloyed titanium
ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
USP 37th ed. 2014<85> Bacterial Endotoxins Test
USP 37th ed. 2014<151> Pyrogen Test
ISO 14698-1:2003 Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods
ISO 14644-1:1999 Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness
ISO 14644-3:2005 Cleanrooms and associated controlled environments - Part 3: Test methods

ISO 11737-1:2006 (R)2011 Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on product, 2ed
ISO 11737-2:2009 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11607-1:2006/(R)2010 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2006/(R)2010 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11137-1:2006/(R) 2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
ISO 11137-2:2012 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11137-3:2006/(R)2010 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects.
ASTM F1980-07 (Reapproved 2011), Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices. (Sterility).
ANSI / AAMI ST79: 2010& A1:2010 & A2:2011 & A3:2012 & A4:2013 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Comparison of Technological Characteristics

Table 1: General Implant Device Comparison

Characteristic	Subject Device	Own predicate	Predicate Device	SE / Comments
Device	Microdent Ektos implant	Microdent Genius implant (K141188)	Legacy System Dental Implants (K073033)	Yes (Microdent Ektos and Legacy have the same hex connection. Microdent Genius has connection tapered with indexation, rest of characteristics same as Microdent Ektos)
Intended	Microdent Ektos Implant	Microdent Genius Implant	The intended use of the	Yes (Microdent

use	System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla and mandible.	System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	Legacy System Implants with HA Coating is identical to the intended use of the predicate abutments. These implants are two-piece implants for single-stage or two-stage surgical procedures. The Legacy implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.	Ektos specified the use of small diameter implants, Legacy System are coated blasted or HA plasma)
Indication	Delayed or inmediate load	same	same	Yes
Material	Comercially pure titanium (grade 4 as ISO 5832-2)	same	Titanium Alloy (grade 5 as ISO 5832-3)	Yes (Different degree but with very similar properties)
Design;	Threaded, root form implant. 	same 	same 	Yes (Legacy implant has quadruple-lead threads near top)
Length (mm)	8, 10, 12, 14, 16 and 18 mm.	8, 10, 12, 14, 16 and 18 mm.	8, 10, 11.5, 13 and 16 mm	Yes
Platform	Diameter ranges: 3.5 mm, 4.5 mm and 5.7 mm.	Diameter ranges: 3.5 mm, 4.5 mm, 5.0 and 5,5 mm.	Diameter ranges: 3.0 mm, 3.5 mm, 4.5 mm and 5,7	Yes

			mm.	
Diameter (mm)	Diameter ranges: 3.7 mm, 4.2 mm, 4.8 mm, 5.8 mm and 7.00 mm.	Diameter ranges: 3.5 mm, 4.5 mm, 5.0 and 5,5 mm.	Diameter ranges: 3.2 mm, 3.7 mm, 4.2 mm, 4.7 mm, 5,2 mm, 5.7 mm and 7.0 mm.	Yes
Connection type	Internal connection with hex.	Internal connection tapered with indexation.	Internal connection with hex.	Yes with Legacy (Hex connection) Different connection from Genius implant
Surface treatment	Blasting (roughness 0,82 µm peak-to-valley).	same	SBM (Soluble Blast Media) or HA-coated. (SBM roughness 1.5-2.3 µm peak-to-valley).	Yes (Blasted treatment with similar result)
Sterilization	Sterile (Gamma irradiation)	same	same	Yes
Packaging	Inner sleeve to suspend the implant/fixture-mount assembly packaged inside an outer vial sealed with a cap. Packaging also includes surgical cover screw and multi-function abutment.	Packaged in sterile vial with cover screw	Inner sleeve to suspend the implant/fixture-mount assembly packaged inside an outer vial sealed with a cap. Packaging also includes surgical cover screw, extender and temporary coping.	Yes (but Legacy includes an extender)
Shelf Life	5 years	same	same	Yes
Mating Components	All Microdent Restorative Components	All Microdent Restorative Components	All Legacy Restorative Components	Yes

Table 2: General Prosthetic Device Comparison

Characteristic	Subject Device	Own predicate	Predicate Device	SE / Comments
Device Name	Microdent Ektos implant abutments	Microdent Genius implant abutments	Legacy Abutment System	yes
510K	NA	K141188	K060063	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	Yes (Ektos Microdent specified the use of small diameter implants.).
Material	Titanium alloy (Grade 5).	same	Titanium alloy.	Yes
Surface treatment	Polished.	same	same	Yes
Sterilization	Non-sterile	same	same	Yes
Packaging	Blister	same	same	Yes

Device Name	Microdent Ektos cover screw	Microdent Genius cover screw	Legacy cover screw	Yes

510K	NA	K141188	K073033	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The intended use of the Legacy System Implants with HA Coating is identical to the intended use of the predicate abutments. These implants are two-piece implants for single-stage or two-stage surgical procedures. The Legacy implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.	Yes (Microdent Ektos specified the use of small diameter implants, Legacy System are coated blasted or HA plasma)
Design;	3 diameters and metric thread M1.8	One diameter	same	Yes (Microdent Genius has one diameter and smaller)
Collar Height (mm, min -max)	Without heights	same	same	Yes
Seating Surface (mm)	Diameter 3.5 mm, 4.5 mm and 5.7 mm.	Diameter 2.9 mm.	same	Yes (Microdent Genius has one diameter and smaller)
Connection type	Internal connection tapered.		Internal connection tapered.	Yes
Sterilization	Sterile (Gamma irradiation)	same	same	Yes. Packaged sterile with the implant

Device Name	Microdent Ektos Healing Abutment	Microdent Genius Healing Abutment	Legacy Healing Collar	yes
510K	NA	K141188	K060063	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	Yes (Ektos Microdent specified the use of small diameter implants).
Design;	4 diameters and metric thread M1.8	One diameter	One diameter and metric thread M1.8	Yes
Collar Height (mm, min -max)	0 mm to 4 mm	1 mm to 6 mm	3 and 5 mm	Yes
Seating Surface (mm)	Diameter from 3.5, 4.5, 5.6 and 6.5 mm.	Diameter from 4.5, 5 and 5.5 mm.	Diameter from 3.7, 4.7, 5.7 and 6.5 mm.	Yes
Connection	Internal connection	same	same	Yes

type	tapered.			

Device Name	Microdent Ektos Retention screw	Microdent Genius Retention screw	Legacy Fixation screw	Yes
510K	NA	K141188	K060063	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	Yes (Ektos Microdent specified the use of small diameter implants).
Design;	This screw having a threaded fuse and a head with a hexagon 1.20 mm flat to flat.	same	same	Yes
Seating Surface (mm)	This is a single Retention screw for all platforms	same	same	Yes

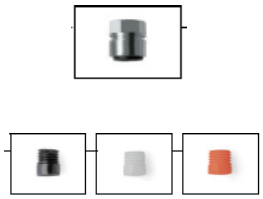
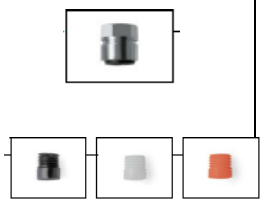
Device Name	Microdent Ektos Conical abutment	Microdent Genius Conical abutment	Legacy straight abutments	Yes
510K	NA	K141188	K060063	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	Yes (Ektos Microdent specified the use of small diameter implants)
Design	3 diameters and hex connection (Microdent Ektos). Abutment with flap and without flap.	3 diameters and same connection (Microdent Genius). Abutment with flap and without flap.	4 diameters and hex connection (Legacy). Abutments Contoured and Full-contoured.	Yes, but Microdent Ektos and Legacy have the same hex connection. Microdent Genius has connection tapered with

	Microdent Ektos inmediate loading abutment with slots on outer taper surface. Multifunction abutment.	Microdent Genius inmediate loading abutment with slots on outer taper surface. Not available.	Design for inmediate loading is called Titanium Temporany Abutments and have not slots on taper surface. Fixture-Mount.	indexation, rest of characteristics same to Microdent Ektos. Yes, but Fixture-Mount has the same function than multifunction abutment using two pieces.
Collar Height (mm, min -max)	1 mm to 5 mm	1 mm to 6 mm	1 , 2 and 3 mm	Yes (Legacy has not height 4 and 5 mm, but Genius yes)
Seating Surface (mm)	Diameter from 4.5, 5.6 and 6.2 mm.	Diameter from 4.5, 5 and 5.5 mm.	Diameter from 3.7, 4.7, 5.7 and 6.5 mm.	Yes
Connection type	Internal hex connection (H) or circular (R).	Internal connection tapered with indexation (H) or only tapered (R).	Internal hex connection (Engaging) or Non-Engaging.	Yes Microdent Ektos and Legacy have the same hex connection. Microdent Genius has connection tapered with indexation, rest of characteristics same to Microdent Ektos.

Device Name	Microdent Ektos Mini Capitel abutment	Microdent Genius Mini Capitel abutment	Legacy Screw-Receiving Overdenture Abutments	Yes
510K	NA	K141188	K060063	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters,lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	Yes (Ektos Microdent specified the use of small diameter implants.)
Design	One prosthetic diameter of 4,8 mm.	One prosthetic diameter of 4,8 mm.	One prosthetic diameter of 5 mm.	Yes
Collar Height (mm, min	1 mm to 4 mm	1 mm to 6 mm	1 , 2 and 4 mm	Yes

-max)				
Seating Surface (mm)	Diameter ranges: 3.5 mm, 4.5 mm and 5.7 mm.	Diameter ranges: 3.5 mm, 4.5 mm, 5.0 and 5,5 mm.	Diameter ranges: 3.0, 3.5 mm, 4.5 mm and 5.7 mm.	Yes
Connection type	Internal connection tapered (R).	Internal connection tapered (R).	Internal connection tapered (Non-engaging)	Yes (These Ektos abutments are used only for multiple screw prosthesis)
Copings	Cementable coping of Titanium (Grade 5).	Cementable coping of Titanium (Grade 5)	Two cementable coping of Gold and titanium. Plastic coping. Gold&Plastic Coping. Titanium Temporary Coping.	Yes (Legacy has more components)

Device Name	Microdent Ektos Osscilia retention abutment	Microdent Genius Osscilia retention abutment	Legacy Ball Abutments	Yes
510K	NA	K141188	K060063	Yes
Intended use	Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxilla a nd mandible.	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and 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. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters,lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	Yes (Ektos Microdent specified the use of small diameter implants.)
Design;	Diameter ranges: 3.5 mm, 4.5 mm and 5.7 mm. Compensation 17º.	One prosthetic diameter of 3.5 mm. Compensation 17º.	Diameter ranges: 3.5 mm, 4.5 mm and 5.7 mm. Compensation 28º.	Yes
Retention:	Three types of retainers (with	Three types of retainers (with	Housing and a type	Yes

	dimensional variations) varies the cap retainer. 	dimensional variations) varies the cap retainer. 	of retainer. 	(Microdent Genius and Ektos have 3 retainers with different friction and Legacy only one.)
Collar Height (mm, min -max)	0 mm to 4 mm	1 mm to 6 mm	2 and 4 mm.	Yes
Seating Surface (mm)	Diameters 3.5 mm, 4.5 mm and 5.7 mm.	Diameter 3.5 mm.	Diameters 3.5 mm, 4.5 mm and 5.7 mm.	Yes
Connection type	Internal connection tapered.	Internal connection tapered.	Internal connection tapered.	Yes

Microdent Ektos Implant System is substantially equivalent intended use as the identified predicates. Microdent Ektos Implant System is similar in fundamental scientific technology to the predicate devices in that they all have been designed, manufactured and tested in compliance with FDA'S Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Microdent Ektos Implant System is substantially equivalent in materials, indications and intended use, packaging, labeling and performance to the predicate devices currently marketed in the U.S.

The only differences the subject device and the predicate are slight differences in design and dimensions with Legacy and the connection type with Genius.

Non-Clinical performance tests

The proposed devices have been subject to bench testing to determine fulfillment of design and performance requirements. Bench testing followed the recommendations provided in FDA Guidance Document – Class II Special Controls Guidance Document for Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Specific performance testing on the EKTOS implant system included:

- Static and dynamic fatigue testing in accordance with ISO 14801;
- Sterilization validation has been performed following standards ISO 11137-1 and ISO 11137-2.

Test data from the predicate device Microdent GENIUS implant system was leveraged for the following performance tests based on the use of identical implant and packaging materials as well as identical manufacturing, packaging and cleaning processes for the Microdent EKTOS implant system:

- Biocompatibility evaluation in accordance with ISO 10993-1 and specifically cytotoxicity testing in accordance with ISO 10993-5;
- Package integrity testing in accordance with ASTM F-1980-07;
- Pyrogen testing in accordance with USP <151>
- Bacterial endotoxin LAL test USP <85>
- ESEM analyses to determine adequate surface finish and roughness
- EDS analyses to determine adequate surface cleaning
- TOC analyses to determine adequate surface cleaning

All specific non-clinical testing demonstrated that the Microdent EKTOS implant system fulfills the related requirements. In addition, all leveraged non-clinical testing demonstrated that materials and processes identical to those used for the Microdent EKTOS implant system fulfilled the related requirements.

G. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the determination of substantial equivalence.

H. Conclusion of Substantial Equivalence

Based on the similarities observed and results of non-clinical testing performed, we conclude that the proposed devices are substantially equivalent to the predicate devices.