April 22, 2021

Implants Diffusion International
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K200329
Trade/Device Name: IDCAM Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 18, 2021
Received: March 23, 2021

Dear Angela Blackwell:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200329

Device Name
IDCAM Dental Implants

Indications for Use *(Describe)*
IDCAM Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth , in order to restore patients esthetics and chewing function. IDCAM implants are intended for single or multiple unit restorations on splinted or non-splinted applications. They are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.

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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510k Summary
April 21, 2021
IDCAM Dental Implants
K200329

Name and address: Implants Diffusion International
23 rue Emile Zola
Montreuil France 93100
Contact Person: Rony Boukhris
Phone Number: +33 (0) 148707048
Name of device: IDCAM Dental Implants
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA

Submission Contact:
Angela Blackwell
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Device Description: The ID CAM Dental Implant is a tapered conical implant system with two designs. IDCAM M (with mini-threads), and IDCAM ST. IDCAM ST has large flat threads at the top and sharp threads at the bottom and comes in diameters of 3.7, 3.9, 4.2 and 5.2 mm. Lengths of 9.4, 11.4, and 14.4 mm are available. The IDCAM M has mini-threads at the top and with sharp threads below. It comes in 4.2, and 5.2 mm diameter with lengths of 8.5,9.4, 11.4, and 14.4mm. The bottom of both IDCAM designs is convex.

All implants and abutments are made of ASTM F136 Ti 6Al 4V ELI. The implants have a grit blasted and acid etched surface.

ID CAM abutments for single unit restorations are all attached by Morse taper fit as well as a screw. Morse taper cone straight abutments come in 3.6 and 4.2mm diameter with gingival heights of 1.4, 3, and 5mm. Morse taper cone shouldered straight abutments come in 5.4mm diameter at the upper platform with a 3.6mm diameter at the platform bottom and gingival

heights of 1.3, 2.2, 3.2, and 5mm. Morse taper angled cone abutments come in 7°, 15°, and 23° angles in diameters of 3.6 and 4.2 and gingival heights of 1.4 (7° only) or 1.63 (15° and 23°), 3, and 5mm. Morse taper angled cones abutments with shoulder come in 7°, 15°, and 23° angles in a diameter of 5.4 at the upper platform with a 3.6mm diameter at platform bottom and gingival heights of 0.9, 3, and 5mm in 7°, and gingival heights of 0.9, 2.35, 3.30, and 5.03mm in 15°, and 23°.

PLAN abutments in 5.4mm diameter at shoulder top with a 3.6mm diameter at shoulder bottom and come in gingival heights of 1.5 and 3mm and there are straight, 15°, and 23° versions. Plan abutments can be used for single or multiple unit restorations but are not used for removable prostheses.

Straight IDUnit abutments, angled IDUnit abutments, IDLoc abutments, and ball attachments are permanent threaded abutments which are for multi-restorations only. IDLOC is 3.6mm diameter at platform and comes in gingival heights of 2.5, 4, 5.5, and 7.5 mm. Ball attachments are in 3.5 diameter and come in gingival heights of 1, 2.5, 4, or 6mm. Straight IDUnits are in 3.6mm diameter with 4.9mm diameter at top of shoulder and come in gingival heights of 1, 2.5, 4 or 6 mm. 17° angled IDUnits come in 3.6mm diameter with 4.9mm diameter at top of shoulder and in a gingival heights of 1.35,3.02 or 5 mm. 30° angled IDUnits come in 3.6mm diameter with a 4.9mm diameter at top of shoulder and in a gingival heights of 1,3.01 or 5 mm. Straight and angled IDUnit mounted dentures can only be removed by the dentist, but dentures mounted on IDLoc or ball attachments can be removed by the patient.

Provisory abutments are temporary use abutments which allow placement of a temporary restoration. These come in 3.6mm diameter and varieties of nonrotational (4.8mm diameter at top of shoulder, gingival height of 1.5mm and post height of 7.5mm), nonrotational tall (4mm diameter at top of shoulder, gingival height of 1.5mm and post height of 12.5mm), rotational (gingival height of 1.5mm and post height of 7.5mm) and provisory IDUnit (4.9mm diameter at the base and a post height of 10.5mm).

Healing caps are temporary use abutments used during the healing phase which come in different gingival heights shapes in order to account for tissue thickness differences and space differences. Cylindrical shape healing caps come in diameters of 3.2mm with heights of 3.5 and 5mm, 4 & 5 mm with heights of 2, 4, 6, and 8mm. Conical profile healing caps come in 3.6mm diameter at the platform with a 6mm cone top diameter and 4mm gingival height, or a 3.6mm diameter at platform with a 6mm cone top diameter and gingival height of 6mm. There is also a healing cap for the IDUnit.

Indications for Use: IDCAM Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth , in order to restore patients esthetics and chewing function. IDCAM implants are intended for single or multiple unit restorations on splinted or non-splinted applications. They

are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.

Testing Summary: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments and implants are strong enough for their intended use. IDCAM implants exhibited a run out limit equivalent to other implant systems. Surface modification information was provided per the FDA Guidance Document for Endosseous Dental Implants and Abutments. Surface analysis and cytotoxicity testing per ISO 10993-5 was done to show the surface treatment does not adversely change the biocompatibility of the materials. All the materials are ones common in dental implant systems and are appropriate materials for devices used with dental implants. Implants and abutments are made of titanium alloy which meets ASTM F136. Sterilization validation was conducted on the implants per ISO 11137-1,-2,and -3. Abutment steam sterilization validation was done per ISO 17665-1, ISO 17665-2 and ANSI/AAMI ST79. Package integrity testing and accelerated aging were conducted per ISO 11607-1 and -2. Endotoxin testing according to USP 161 was conducted.

Primary Predicate Device: SpiralTech Dental Implant System Ultimate Conical K170372
Reference Predicates: Cortex K090709 and K163385

Substantial Equivalence:
IDCAM Dental Implants are substantially equivalent to SpiralTech Dental Implant System in indications for use, materials, design, and fatigue performance.

Implant System Comparison Table	ID CAM Dental Implants (Subject Device)	SpiralTech Dental Implant System K170372 Ultimate Conical
Indications for Use	IDCAM Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth , in order to restore patients esthetics and chewing function.	The Spiraltech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Spiraltech implants are intended for single

	IDCAM implants are intended for single or multiple unit restorations on splinted or non-splinted applications. They are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.	or multiple unit restorations on splinted or non-splinted applications. The implants ESi Dynamic and Ultimate are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period. Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.0 and/or 3.3 implants adjacent to one another.
Material	Ti6Al4V	Ti6Al4V
IDCAM M		
Diameter of Implants	4.2, 5.2	3.0, 3.5, 4.3, 5.0, 6.0
Implant Lengths	8.5, 9.4, 11.4, 14.4	8, 10, 11.5, 13, 15 (3.0mm diameter not in 8 length)

Surface Treatment	SLA	SLA or RBM
Sterilization of Implants	Provided sterile by gamma irradiation	Provided sterile by gamma irradiation
Sterilization of abutments	Provided non-sterile with instructions for user to sterilize them	Provided non-sterile with instructions for user to sterilize them
Connection	Conical	Conical
Spiral Implant Design	IDCAM M	Ultimate Conical
ISO 14801 Fatigue Test	Run out limit is the same or higher than those of other implant systems	Run out limit is comparable to other implant systems.
IDCAM ST		
Diameter of Implants	3.7, 3.9, 4.2, 5.2	3.0, 3.5, 4.3, 5.0, 6.0
Implant Lengths	9.4, 11.4, 14.4	8, 10, 11.5, 13, 15 (3.0mm diameter not in 8 length)
Surface Treatment	SLA	SLA or RBM
Sterilization of Implants	Provided sterile by gamma irradiation	Provided sterile by gamma irradiation
Sterilization of abutments	Provided non-sterile with instructions for user to sterilize them	Provided non-sterile with instructions for user to sterilize them
Connection	Conical	Conical
Spiral Implant Design	IDCAM ST	Ultimate Conical
ISO 14801 Fatigue Test	Run out limit is the same or higher than those of other implant systems	Run out limit is comparable to other implant systems.

Conical Implant Parts	**IDCAM Dental Implants**	**SpiralTech Dental Implant System Conical Connection Parts**	**Cortex K090709 and K163385 Conical Connection Parts**
Cover screw	Cover screw for IDCAM 3.6mm diameter	Cover screw NP and RP	

Abutment screw	IDCAM and IDUnit 3.6mm abutment screws	NP and RP abutment screws	
Multi-Unit Abutments*	IDUnit 3.6mm diameter at platform 4.9mm diameter at top of shoulder abutments in gingival heights of 1,2.5, 4, and 6 mm		NP, RP, and WP Multi-unit abutments in heights of 1, 2, 3, 4, and 5 mm
17° Multi-Unit Abutments *	IDUnit 17° Multi-Unit Abutments 3.6mm diameter at platform 4.9mm diameter at top of shoulder in gingival heights of 1.35,3.02, 5 mm		NP and RP 18° Multi-Unit Abutments in heights of 1, 2, 3, 4, 5 mm
30° Multi-Unit Abutments *	IDUnit 30° Multi-Unit Abutments 3.6mm diameter at platform 4.9mm diameter at top of shoulder in gingival heights of 1,3.01, 5 mm		NP and RP 30° Multi-Unit Abutments in heights of 1, 2, 3, 4, 5 mm
Ball attachments*	3.5 mm diameter at platform in gingival heights of 1, 2.5, 4, and 6mm	NP and RP Ball attachments in heights of 1,2,3,4,5, and 6mm	
Healing Caps NP	Cylindrical Healing Cap Narrow 3.2mm diameter in 3.5,5.5 mm gingival heights	NP Healing Cap in 2,3,4,5 and 6 mm height	
Healing Caps RP	Cylindrical Healing Cap Regular 4mm	RP Healing Cap in 2,3,4,5, and 6 mm height	

	diameter in 2,4, 6 and 8 mm gingival heights		
Healing Cap WP	Cylindrical Healing Cap Wide 5mm diameter in 2, 4, 6, 8mm gingival heights		5.8mm Healing cap in 3,4,5,6 mm
Conical Profile Healing Cap Regular	3.6mm diameter at platform 4mm cone top diameter and 6 mm gingival height	NP Healing Cap in 2,3,4,5 and 6 mm height	
Conical Profile Healing Cap Wide	3.6mm diameter at platform 6mm cone top diameter and 6 mm gingival height	NP Healing Cap in 2,3,4,5 and 6 mm height	
Healing Cap for Multi-Unit	IDUnit healing cap		Titanium healing cap for multi-unit 5.0mm diameter 4.8mm height
Straight Abutment	Morse taper cone straight abutment 3.6,4.2mm diameter at platform gingival heights of 1.4, 3,5 mm	RP Flat Standard Abutment with height of 6,7,9 and 11 mm	
WP Shoulder Abutment	Morse taper shouldered straight cone abutment 5.4mm diameter at upper platform 3.6 mm diameter at platform bottom gingival	NP and RP Flat with straight shoulder abutment in heights of 1,2, and 3 mm	WP anatomic abutment 5.8mm diameter in heights of 1, 2, 3, and 4mm

	heights of 1.3,2.2 3.2, 5 mm Height between platform top and bottom 3.7 + gingival height		
NP and RP 7° Abutment	Morse taper 7° angled cone abutment 3.6 and 4.2mm diameter with gingival heights of 1.4,3,5 mm	NP and RP 15° Abutment with heights of 1,2,3 mm	NP and RP 15° Anatomic Abutment with heights of 1,2,3, 4 mm
WP 7° Abutment with shoulder	Morse taper 7° angled cone abutment with shoulder 5.4 mm diameter at upper platform 3.6mm diameter at platform bottom gingival heights of 0.9,3,5 mm Height between platform top and bottom 3.7 + gingival height		WP 15° Anatomic Abutment with heights of 1,2,3, 4 mm
NP and RP 15° Abutment	Morse taper 15° angled cone abutment 3.6 and 4.2mm diameter with gingival heights of 1.63, 3, 5 mm	NP and RP 15° Abutment with heights of 1,2,3 mm	NP and RP 15° Anatomic Abutment with heights of 1,2,3, 4 mm
WP 15° Abutment with shoulder	Morse taper 15° angled cone abutment with shoulder 5.4 mm diameter at upper platform 3.6mm diameter at platform bottom		WP 15° Anatomic Abutment with heights of 1,2,3, 4 mm

	gingival heights of 0.9, 2.35, 3.30, 5.03 mm Height between platform top and bottom 3.7 + gingival height		
NP and RP 23° Abutment	Morse taper 23° angled cone abutment 3.6 and 4.2mm diameter gingival heights of 1.63, 3, 5 mm	NP and RP 25° Abutment with heights of 1,2, and 3mm	NP and RP 25° Anatomic Abutment with heights of 2,3, 4 mm
WP 23° Abutment with shoulder	Morse taper 23° angled cone abutment with shoulder 5.4 mm diameter at upper platform 3.6mm diameter at bottom of platform gingival heights of 0.9, 2.35, 3.3, 5.03 mm Height between platform top and bottom 3.7 + gingival height		WP 25° Anatomic Abutment with heights of 1,2,3, 4 mm
Locator Abutments *	IDLoc attachment 3.6mm diameter at platformi gingival heights of 2.5,4, 5.5, and 7.5 mm	IPI NP and RP in heights of 1,2,3,4,5 and 6 mm	
WP Straight Abutment with shoulder	Plan straight abutment with shoulder 5.4mm diameter at shoulder top 3.6mm diameter at shoulder bottom		WP anatomic abutment 5.8mm diameter in heights of 1, 2, 3, and 4mm

	gingival heights of 1.5 and 3mm		
WP 15° angled abutment with shoulder	Plan 15° angled abutment with shoulder 5.4mm diameter at shoulder top 3.6mm diameter at shoulder bottom gingival heights of 1.5 and 3mm		WP 15° Anatomic Abutment with heights of 1,2,3, 4 mm
WP 23° angled abutment with shoulder	Plan 23° angled abutment with shoulder 5.4mm diameter at shoulder top 3.6mm diameter at shoulder bottom gingival heights of 1.5 and 3mm		WP 25° Anatomic Abutment with heights of 1,2,3, 4 mm
Temporary Abutments	3.6mm diameter provisional abutments in rotational (gingival height 1.5, post height 7.5), non-rotational (gingival height 1.5, post height 7.5, 4.8mm diameter at top of shoulder), non-rotational tall (gingival height 1.5mm, post height 12.5mm, 4.0mm diameter at top of shoulder) and IDUnit (4.9 mm		Nobel Biocare K161435 Temporary Snap Abutments engaging, non-engaging, and multi-unit

	diameter at base, post height 10.5)		

***These models of abutments are not for single crown use.**

Conclusion:

IDCAM Dental Implants are substantially equivalent to SpiralTech Dental Implant System. They both have the same indications for use, are of the same material, and have conical connections. Performance testing demonstrates substantial equivalence to the identified predicate devices. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Any abutments not found in the predicate device system are found in the reference device system. The design and size differences between predicate or reference devices and the subject devices are only minor differences in geometry and size so given the use, materials and technology is the same they do not change the substantial equivalence.