February 20, 2020

SDS Swiss Dental Solutions AG
Martin Chares
CTO
Konstanzerstrasse 11
Kreuzlingen, 8280
SWITZERLAND

Re: K190406
Trade/Device Name: SDS2.2 dental implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 17, 2020
Received: January 21, 2020

Dear Martin Chares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K190406

Device Name
SDS2.2 dental implant

Indications for Use *(Describe)*

SDS2.2 dental implants are intended as artificial replacements to be placed in the human upper or lower jaw to provide anchor points for the prosthetic restoration. They are indicated for transgingival healing. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

SDS2.2 standard implant posts and SDS2.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS2.2 dental implant and enable the fixation of prosthetic restorations.

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	SDS SWISS DENTAL SOLUTIONS

510(k) number: K190406

1. Submitters contact information:

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Contact person: Dr. Martin Chares
Date prepared: 02-19-2020

2. Device name and classification

Trade Name: SDS2.2 dental implant
Common Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 21 CFR 872.3640
Classification: Class II

3. Predicate devices

3.1 Primary predicate device SDS2.2 dental implant

	Device Owner/ Trade Name	510(k) #	Product Code
Primary Predicate Device	SDS Swiss Dental Solutions AG/ SDS1.2 dental implants	K181953	DZE (Implant, Endosseous, Root-Form)

3.2 Reference devices SDS2.2 dental implant

	Device Owner/ Trade Name	510(k) #	Product Code
Reference Device	TAV Medical Ltd./ W Zirconia Implants	K172668	DZE (Implant, Endosseous, Root-Form)
Reference Device	Z-Systems AG Z5c Dental Implant	K132881	DZE (Implant, Endosseous, Root-Form)
Reference Device	Dental Point AG Zeramex® P6 Dental Implant System	K163043	DZE (Implant, Endosseous, Root-Form)

3.3 Reference Devices SDS2.2 implant post

	Device Owner/ Trade Name	510(k) #	Product Code
Reference Device	Z-Systems AG Z5c Abutment	K132881	NHA (Endosseous Dental Implant Abutment)
Reference Device	TAV Medical Ltd. Titanium Abutment	K172668	NHA (Endosseous Dental Implant Abutment)
Reference Device	Dental Point AG Zeramex® P6 Abutment	K163043	NHA (Endosseous Dental Implant Abutment)

4. Device description

4.1 SDS2.2 dental implant

SDS2.2 dental implants are a two-piece implant system to fit a synthetic root replacement into the human jaw.
The implants are made of Y-TZP (yttria-stabilized tetragonal zirconia poly-crystal) zirconium dioxide ceramics in accordance with ISO 13356.
The SDS2.2 dental implant system with its included components is used to fix the prosthetic restoration and is suitable for patients with an intolerance to metal.
The implants have a self-tapping Dynamic Thread® in the lower section of the implant for good primary stability. Its bone-condensing section has a 2.5x thread depth. The upper section of the implant has a micro-thread. The outer surface of the SDS2.2 implants is abrasive blasted for good osseointegration, the implant shoulder is machined.

SDS2.2 implants are provided in different length/ diameter combinations:

Length	Apical diameter	Coronal diameter
8 mm	3.8 mm 4.6mm	5.0 mm 6.0 mm
11 mm	3.8 mm 4.6 mm 5.4 mm	5.0 mm 6.0 mm 6.0 mm
14 mm	3.8 mm 4.6 mm 5.4 mm	5.0 mm 6.0 mm 6.0 mm

SDS2.2 implants are provided with 2 different shoulder designs, available in either standard shoulder and oval shoulder. These different designs allow for insertion in interdental gaps of different dimensions. The same surgical technique is used for both implant shoulder designs.

The implants are provided sterile in sterile packaging and are intended for single use. SDS2.2 dental implants must not be re-sterilized or disinfected either.
The sterile packaging also includes the SDS2.2 cover screw made of PEEK (Polyetheretherketone), which can be used to protect the implant interface during the healing phase up to 180 days.
SDS2.2 cover screw is intended for single-use and must not be re-sterilized or disinfected either.

4.2 SDS 2.2 standard implant post/ SDS2.2 standard PEEK screw

SDS2.2 standard implant posts are made of Y-TZP and are attached to SDS 2.2 dental implants by cementation. During cementation, the implant posts are screw retained with the SDS2.2 standard PEEK screw to ensure implant post is fixed at final position. The SDS2.2 standard PEEK screw is removed before the cement is completely cured.
After attachment to the SDS2.2 implant, standard implant posts enable cementation of prosthetic restorations.
SDS2.2 standard implant posts are available in different designs:

	SDS2.2_AB-S+1.5	**SDS_AB-S15°**
Diameter	4.1 mm	4.1 mm
Post height	4.9 mm	7.0 mm
Angulation	None	15°

The SDS2.2 standard implant posts and SDS2.2 standard PEEK screws are provided non-sterile. They are intended for single use and must not be reused. Before use they must be cleaned, disinfected and sterilized according to the instructions given in the “Instructions for the use of SDS2.2 implant posts/ standard screws” document.

5. Indications for use

	Subject device K190406	**Primary predicate device K181953**
Indications for Use	SDS2.2 dental implants are intended as artificial replacements to be placed in the human upper or lower jaw to provide anchor points for the prosthetic restoration. They are indicated for transgingival healing. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. SDS2.2 standard implant posts and SDS2.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS2.2 dental implant and enable the fixation of prosthetic restorations.	SDS1.2 dental implants are intended as artificial replacements to be placed in the human upper or lower jaw to provide anchor points for the prosthetic restoration. They are indicated for transgingival healing. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. SDS1.2_33xx implants are recommended as single-tooth implant for upper lateral and lower incisors for fixed prosthetic restorations only. SDS1.2 healing caps-disc, SDS1.2 temporary caps and SDS1.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS1.2 dental implant and enable the production/ fixation of long-term temporary restorations or protect the implant during the healing phase for up to 180 days.

The Indications for Use of the subject device are the same as of the primary predicate device with only some minor differences as further discussed below.

- The Indications for Use of the primary predicate device contains a limitation for the use of the smallest diameter implant body and a statement about further components. As the subject device's smallest implant diameter is 5.0 mm, the limitation for the use of the smallest diameter implant body of the primary predicate device is not applicable to the subject device.
- The prosthetic components are different due to the Two-piece design of the subject device compared to the One-piece design of the primary predicate device. The use of these components with the subject device are consistent with the use of similar components of the primary predicate device and therefore do not raise new questions of safety and effectiveness when compared to the predicate device.

Below reference devices were also used in this premarket notification to capture technological characteristics found in the subject device that were not present in the primary predicate device (due to its One-piece design). These minor differences in technological characteristics as identified in the table below do not raise any new questions of safety and effectiveness between the subject and primary predicate device, as these differences are present in the reference devices, which have undergone FDA review and are legally marketed in the US.

6. Technological characteristics

Manu-facturer:	SDS Swiss Dental Solutions AG (K190406)		SDS Swiss Dental Solutions AG (K181953)		TAV Medical Ltd. (K172668)		Z-Systems AG (K132881		Dentalpoint AG (K163043)	
	Subject Device		Primary Predi-cate Device		Reference Device		Reference Device		Reference Device	
Trade Name	SDS2.2 dental implant		SDS1.2 dental implant		W Zirconia Implants		Z5c		Zeramex® P6	
Material	Y-TZP		Y-TZP		Y-TZP		Y-TZP		ZrO2-ATZ-HIP	
Manu-facturing Technology	Turning		Turning		CIM: Ceramic injection molding		Turning		Turning	
Implant Length	8.0 mm 11.0 mm 14.0 mm		8.0 mm 11.0 mm 14.0 mm		8.0 mm 10.0 mm 12.0 mm		8.0 mm 10.0 mm 12.0 mm		8.0 mm 10.0 mm 12.0 mm 14.0 mm	
Implant Diameter (coronal)	5.0 mm 6.0 mm		4.2 mm 5.0 mm 6.0 mm		4.1 mm 4.8 mm		5.0 mm 6.0 mm		3.3 mm 4.1 mm 4.8 mm	
Types	Length/ mm	Ø/ mm	Length/ mm	Ø/ mm	Length/ mm	Ø/ mm	Length/ mm	Ø/ mm	Length/ mm	Ø/ mm
	8	5.0 6.0	8	5.0 6.0	8	4.1 4.8	8	4.0 5.0	8	3.3 4.1 4.8
	11	5.0 6.0	11	4.2 5.0 6.0	10	4.1 4.8	10	4.0 5.0	10	3.3 4.1 4.8
	14	5.0 6.0	14	4.2 5.0 6.0	12	4.1 4.8	12	4.0 5.0	12	3.3 4.1 4.8

									14	3.3 4.1 4.8
Angulation/ Divergence	Possible up to 15° when using the standard implant post SDS_AB-S15°		Possible up to 20°		no information available		no information available		no information available	
Design	Two-piece		One-Piece		One-Piece/ Two-Piece		Two-Piece		Two-piece	
Shoulder design	Standard shoulder Oval shoulder		Standard shoulder Oval shoulder		Standard shoulder		Standard shoulder		Standard shoulder	
Implant Surface Treatment	Sand blasted		Sand blasted		no additional treatment		Grit blasted and laser modified		ZERAFIL™ sandblasted and etched	
Surface Topography	Roughness		Roughness		Roughness		Roughness		Roughness	
Sterilization	Sterilized by Radiation		Sterilized by Radiation		Sterilized by Radiation		Plasma sterilization		Steam sterilization	
Intended Use Environmen	Dental Clinic Setting		Dental Clinic Setting		Dental Clinic Setting		Dental Clinic Setting		Dental Clinic Setting	

7. Substantial equivalence discussion

7.1 Substantial equivalence discussion SDS2.2 dental implants

As demonstrated in the substantial equivalence discussion the SDS2.2 subject device is equivalent to the selected predicate devices.

The subject device is equivalent to the primary predicate device in terms of intended use, technological characteristics, material and design key elements (including diameter and length, production technology, implant surface topography, sterile packaging, shoulder design, etc.).

Certain differences from the primary predicate device are covered by the reference devices as follows:

- In terms of anti-rotation protection, the subject device is designed with an internal hexagon, while the primary predicate device features a One-Piece design. This difference is covered by the reference devices K172668 and K163043, which are also providing an internal hexagon for anti-rotation protection.
- Regarding available abutments, the primary predicate device features a One-Piece design that requires no additional abutments. This difference is covered by the reference devices K132881, K172668 and K163043, which are containing abutments in similar designs.

Based on this comparison it can be concluded, that the subject device K190406 is substantially equivalent to the predicate devices listed.

7.2 Substantial equivalence discussion SDS2.2 standard implant posts

As demonstrated in the substantial equivalence discussion the SDS2.2 subject device is equivalent to the selected predicate devices.

SDS2.2 standard implant posts are substantially equivalent in terms of material, intended use, indications for use and geometry to the reference devices listed above.

Certain differences from the reference devices are covered by following facts:

- In terms of length, SDS2.2 standard implant posts are available in a greater length compared to the reference devices. This difference in product height does not raise any performance differences due to the similarity of the subject device to the reference devices K172668 and K163043. Additionally, the increased product height of the SDS2.2 angulated standard implant post has been tested successfully in the context of performed fatigue testing according to ISO 14801.
- Regarding the connection of the abutment to the implant, for the subject device the fixation of the standard implant post during cementation by screw retaining is mandatory while the reference device K132881 does not require screw retaining during this process. This difference is bridged by the reference device K163043, which uses a PEEK screw for retaining of the abutment on the one hand and the fact, that the screw of the subject device is removed before the cement is completely cured on the other hand.
- Regarding the cements used for bonding, SDS2.2 implant posts are recommended to be bonded using the dental cement Ketac™Cem Automix, whereas the reference devices recommend Panavia™ SA Cement Automix and RelyX™ Luting Plus Automix. The difference is bridged by the fact, that all stated dental cements are cleared medical devices, cleared under K032455, K111185 and K002793.
- Additionally, the dental cement Ketac™Cem Automix (K002793) has been tested successfully in the context of performed fatigue testing according to ISO 14801.

Based on this comparison it can be concluded, that the subject device is substantially equivalent to the reference devices listed.

8. Non clinical testing

8.1 Biocompatibility

Concerning biocompatibility, the components of the SDS2.2 dental implant system described in the biocompatibility document were subjected to a biological evaluation according to ISO 10993-1 including cytotoxicity tests according to ISO 10993-5.

For the manufacturing of SDS2.2 dental implant system, identical materials are used in the primary predicate devices with the same type and duration of patient contact (see also substantial equivalence comparison).
Concerning the residues from manufacturing processes, the biocompatibility is demonstrated by the tests regarding Cytotoxicity, Bioburden and Endotoxins by an accredited laboratory.

The methods applied for manufacturing, cleaning and sterilization are established validated procedures since several years and are identical to the methods applied for the primary predicate device, cleared under K181953.

8.2 Performance testing

Performance testing of SDS2.2 dental implant system was planned regarding the risk analysis acc. ISO 14971.
The indicated performance tests were derived and have been projected.

As a result of the risk analysis and regarding the applicable FDA guidance, testing concerning stability, surface structure analysis and several laboratory testing were identified as essential.

In particular, fatigue testing acc. ISO 14801, surface investigation with the aid of the scanning electron microscope and laboratory testing regarding presence of extractable cytotoxic substances, pyrogenicity and total organic carbon have been planned and performed as recommended by the FDA Guidance Document “Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile”.

The testing results were analyzed and evaluated. They demonstrate, that the SDS2.2 dental implant system meets the existing requirements and acceptance criteria like the predicate devices.

8.3 Sterilization validation and shelf life

To ensure the sterility of SDS2.2 dental implants, the sterilization validation was conducted in compliance with ISO 11137-2.
The validation results have proved a minimal sterilization dose of 25 Gy that leads to a sterility assurance level of ≤ 10^{-6} as required by ISO 11137-1 and ISO 11137-2 for sterile medical devices.

For the packaging system a performance validation acc. to ISO 11607-1 and ISO 11607-2 was completed.

The validation results have demonstrated that the packaging system of the SDS2.2 dental implants fulfilled the requirements regarding the packaging performance during sterilization and storage till 5 years accelerated aging.

For the products provided non-sterile, the validation of end-user sterilization has been performed according to ISO 17665-1.

The validation results have demonstrated, that the stated cleaning, disinfection and sterilization process meet the defined results.

9. Animal testing

Not applicable, bench testing is performed

10. Clinical testing

Not applicable, SDS2.2 dental implant system does not meet one of the characteristics defined by FDA for which clinical studies are needed

11. Applicable standards

SDS 2.2 dental implants meet all requirements of the applicable standards listed in the table.

Standard	Title
ISO 14801 Second edition 2007-11-15	Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
ISO 7405 Second edition 2008-12-15	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]
ISO 5832-2:1999	Implants for surgery -- Metallic materials - Part 2: Unalloyed ISO 5832-3 Fourth edition 2016-10-15titanium
ISO 13356	Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015);
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 14971	Medical devices – Application of risk management to medical devices
ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006 + AMD 1.:2014);
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO/ DIS 11607-2:2017)
ISO 11137-1	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including AMD 1:2013)
ISO 11137-2	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

12. Summary

Based on the results of Substantial Equivalence Discussion, Performance testing results and the compliance with applicable standards, the SDS2.2 dental implant system with the included components are considered substantially equivalent to the named predicate devices.

Existing minor differences in design and technology between the subject device and the predicate devices do not raise any new questions of safety and effectiveness. Therefore, it can be concluded that the SDS2.2 dental implant system is substantially equivalent to the predicate devices.