



November 20, 2019

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

Re: K181953

Trade/Device Name: SDS1.2 dental implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 18, 2019
Received: October 22, 2019

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.
Acting 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

Indications for Use

510(k) Number (if known)

K181953

Device Name

SDS1.2 dental implant

Indications for Use (Describe)

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 healing phase for up to 180 days.

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) number: K181953

1. Submitters contact information:

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 Contact person: Dr. Martin Chares
 Date prepared: 11-20-2019

2. Device name and classification

Trade Name: SDS1.2 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 SDS1.2 Dental implant

	Device Owner/ Trade Name	510(k) #	Product Code
Primary Predicate Device	TAV Medical Ltd./ W Zirconia Implants	K172668	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment)

3.2 Reference Devices SDS1.2 Dental implant

	Device Owner/ Trade Name	510(k) #	Product Code
Reference Device	Oral Iceberg S.L./ CeraRoot Implant system	K093595	DZE (Implant, Endosseous, Root-Form)
Reference Device	Z-Systems AG/ Z-Look 3	K062542	DZE (Implant, Endosseous, Root-Form)
Reference Device	Straumann USA LLC Straumann® PURE Ceramic Implants	K171769	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment)
Reference Device	Prismatik Dentalcraft, INC. Hahn Tapered Implant System	K143353	DZE (Implant, Endosseous, Root- Form)

3.3 Primary Predicate Device SDS1.2 Temporary cap

	Device Owner/ Trade Name	510(k) #	Product Code
Primary Predicate Device	TAV Medical Ltd./ Temporary cap	K172668	NHA (Endosseous Dental Implant Abutment)

3.4 Primary Predicate Device SDS1.2 Healing cap-disc

	Device Owner/ Trade Name	510(k) #	Product Code
Primary Predicate Device	TAV Medical Ltd./ PEEK Healing cap for W One Piece Zirconia Implant	K172668	NHA (Endosseous Dental Implant Abutment)

4. Device Description

4.1 SDS1.2 root-form endosseous dental implant

SDS1.2 dental implants are a one-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 SDS1.2 dental implants are used to fix the prosthetic restoration and are 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 SDS1.2 implants is abrasive blasted for good osseointegration, the implant shoulder is machined.

SDS1.2 implants are provided in different length/ diameter combinations:

Length	Apical diameter	Coronal diameter
8 mm	3.8 mm	5.0 mm
	4.6mm	6.0 mm
11 mm	3.25 mm	4.2 mm
	3.8 mm	5.0 mm
	4.6 mm	6.0 mm
	5.4 mm	6.0 mm
14 mm	3.25 mm	4.2 mm
	3.8 mm	5.0 mm
	4.6 mm	6.0 mm
	5.4 mm	6.0 mm

Please note, that the SDS1.2_33xx implant body measures at Ø 3.25 mm.

SDS1.2 implants are provided with 2 different shoulder designs. 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. SDS1.2 dental implants must not be re-sterilized or disinfected either.

When delivered, all SDS1.2 dental implants are mounted with the disposable SDS1.2 insertion tool which allows to remove the dental implant from the sterile packaging without touching it and then insert it into the prepared drill hole.

4.2 SDS 1.2 Temporary cap

Temporary restorations can be produced either individually or by using the prefabricated SDS1.2 Temporary cap as basis.

The SDS1.2 Temporary caps are made of PEEK (polyether ether ketone).

The SDS1.2 Temporary cap may only be used for screw-retaining temporary restorations with SDS1.2 standard screw (SDS1.2_SS-T) and must not be cemented.

The SDS1.2 Temporary caps are provided non-sterile and must be cleaned, disinfected and sterilized according to the instructions given in the “Instructions for use” document. They are intended for single-use and can stay for a maximum period of 180 days in situ.

4.3 SDS1.2 Healing cap-disc

SDS1.2 Healing caps-disc may be used to protect the dental implant.

The Healing caps-disc are made of Y-TZP (yttria-stabilized tetragonal zirconia poly-crystal) zirconium dioxide ceramics in accordance with ISO 13356.

They can be fixed by screw-retaining with SDS1.2 standard titanium screws.

The SDS1.2 Healing caps-disc are provided non-sterile and must be cleaned, disinfected and sterilized according to the instructions provided given in the “Instructions for use” document. They are intended for single-use and can stay for a maximum period of 180 days in situ.

5. Indications for use

	Subject device K181953	Primary predicate device K172668
Indications for Use	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.	TAV Medical’s W Zirconia Implants are intended for surgical placement in the patient’s upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading

	<p>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.</p>	
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The Indications for Use of the subject device is the same as the primary predicate device, and therefore contained within those indications, but also has the following additional differences as further discussed below.

- The Indications for Use of the subject device also contains a limitation for the use of the smallest diameter implant body and a statement about the abutment components. As the primary predicate device's smallest implant diameter is 4.1 mm, the limitation for the use of the smallest diameter implant body of the subject device is equivalent to the limitation of the reference device K062542, with a diameter 3.25 mm to bridge this difference.
- The addition of the healing caps and temporary caps have been added to the Indications for Use for the subject device, as these components can be used during the healing process to protect the implant or to enable the production/ fixation of long-term temporary restorations. 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.

The following reference devices were also used in this premarket notification to capture those technological characteristics found in the subject device that were not present in the primary predicate device and compares them in a side-by-side manner. 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 (K181953)	TAV Medical Ltd. (K172668)	Oral Iceberg S. L. (K093595)	Z-Systems AG (K062542)	Straumann USA LLC (K171769)	Prismatik Dentalcraft Inc. (K143353)
	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
Trade Name	SDS1.2 dental implant	W Zirconia Implants	CeraRoot Implant system	Z-Look 3	Straumann® PURE Ceramic	Hahn Tapered Implant System

510(k) Summary



									Implant Monotype			
Material	Y-TZP		Y-TZP		Y-TZP		Y-TZP		Y-TZP		Ti6Al4 ELI	
Manufacturing Technology	Turning		CIM		Turning		Turning		CIM		Standard manufacturing	
Implant Length	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 14.0 mm		10.0 mm 11.5 mm 13.0 mm 14.0 mm		8.0 mm 10.0 mm 12.0 mm 14.0 mm		8.0 mm 10.0 mm 11.5 mm 13.0 mm 16.0 mm	
Implant Diameter (coronal)	4.2 mm 5.0 mm 6.0 mm		4.1 mm 4.8 mm		3.5 mm 4.1 mm 4.8 mm 6.0 mm 6.5 mm		4.1 mm 5.2 mm 6.0 mm		3.5 mm 4.8 mm		3.0 mm 3.5 mm 4.3 mm 5.0 mm 7.0 mm	
Abutment post height	4 mm		5 mm		3 mm, limited use 4.8 mm 5.0 mm 6.3 mm		5 mm		4 mm 5.5 mm		not-stated	
Types	Length/ mm	Dia- meter/ mm	Length/ mm	Dia- meter/ mm	Length/ mm	Dia- meter/ mm	Length/ mm	Dia- meter/ mm	Length/ mm	Dia- meter/ mm	Length/ mm	Dia- meter/ mm
	8	5.0 6.0	8	4.1 4.8	8	4.8	10	3.25 4.0 4.5	8	3.5 4.8	8	3.5 4.3 5.0 7.0
	11	4.2 5.0 6.0	10	4.1 4.8	10	4.1 4.8 6.0 6.5	11.5	3.25 4.0	10	3.5 4.8	10	3.5 4.3 5.0 7.0
	14	4.2 5.0 6.0	12	4.1 4.8	12	4.1 4.8 6.0 6.5	13.0	3.25	12	3.5 4.8	11.5	3.0 3.5 4.3 5.0 7.0
					14	4.1 4.8 6.0 6.5	14.0	5.0	14	3.5 4.8	13	3.0 3.5 4.3 5.0
											16	3.0 3.5 4.3 5.0
Angulation/Divergence	Possible up to 20°		0° for one-piece zirconia implant		0°		Possible up to 20°		0°		0° – 30°	
Design	One-Piece		One-Piece/Two-Piece		One-Piece		One-Piece		One-Piece		Two-Piece	
Shoulder design	Standard shoulder Oval shoulder		Standard shoulder		Standard shoulder		Standard shoulder		Standard Shoulder		Standard Shoulder	
Implant Surface Treatment	Sand blasted		no additional treatment		ICE® surface		Grit blasted		no additional treatment		Blasted with Hydroxyl Apatit	
Surface Topography	Roughness		Roughness		Roughness		Roughness		Roughness		RBM Surface Technology	

Sterilization	Sterilized by Radiation	Sterilized by Radiation	Sterilization by ethylene oxide	Steam sterilization	Sterilization by ethylene oxide	Sterilization by Gamma irradiation
Intended Use Environment	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting

7. Substantial Equivalence Discussion

7.1 Substantial Equivalence Discussion SDS1.2 Dental implants

As demonstrated in the substantial equivalence discussion the SDS1.2 subject device is equivalent to the selected predicate devices.

The subject device is like the predicate devices in terms of intended use, technological characteristics, packaging, sterilization and design key elements (included implant surface topography, design, etc.).

Certain differences can be covered by reference devices.

In terms of diameter and length there is a difference between the subject device K181953 and the primary predicate device. However, the reference devices K093595, K143353 and K171769 include implants with a similar range of combinations including smallest and largest length with smallest and largest diameter.

In terms of angulation there is a difference between the subject device and the primary predicate device. However, the reference device K062542 allows equivalent angulation application as the subject device.

In terms of packaging the subject and predicate devices are sterile packed, the subject device is in a sealed blister while the primary predicate device is in a sealed tube. The subject device and the reference device K143353 are packaged in a single sealed tray. Both the proposed and primary predicate device are sterilized using Gamma irradiation. The effectiveness of the packaging and sterilization process is verified by a packaging and sterilization validation. A sterility assurance level of $<10^{-6}$ (SAL) is achieved for both devices, therefore the SDS1.2 dental implant is substantially equivalent to the primary predicate device and the reference device for a single tray packaging system.

Based on the comparison it can be concluded, that the SDS1.2 dental implants are substantially equivalent to the predicate devices listed.

7.2 Substantial Equivalence Discussion SDS1.2 Temporary cap

The minor differences in the products diameter do not raise any performance differences due to the similarity of SDS1.2 temporary cap to its predicate device design and range. Therefore, it may be concluded that SDS1.2 temporary cap for SDS1.2 dental implants and its predicate share the same intended use and technological characteristics and therefore are substantially equivalent.

7.3 Substantial Equivalence Discussion SDS1.2 Healing cap-disc

SDS1.2 healing-caps disc are substantially equivalent in terms of intended use, indications for use, geometry and fixation on implant to the predicate PEEK Healing Cap for W One Piece Zirconia Implant. The different material does not represent a restriction. TZP-A used for the SDS1.2 healing cap-disc, is well established in the dental implant market and does not affect

the performance or biocompatibility of the product. This material is also used for the implants itself.

8. Non clinical testing

8.1 Biocompatibility

Concerning biocompatibility, the components of the SDS1.2 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 SDS1.2 dental implant system, identical materials are used in comparable reference 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.

8.2 Performance testing

Performance testing of SDS1.2 dental implant system was planned regarding the risk analysis acc. ISO 14971.

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

In particular; fatigue testing in accordance with ISO 14801 and surface investigation with the aid of the scanning electron microscope and laboratory testing regarding the 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 SDS1.2 Dental implants meet the existing requirements and acceptance criteria like the predicate devices.

8.3 Sterilization validation and shelf life

To ensure the sterility of SDS1.2 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 $\leq 10^{-6}$ as required by DIN EN 556-1 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 SDS1.2 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

10. Clinical testing

Not applicable, SDS1.2 Dental implant does not meet one of the characteristics defined by FDA for which clinical studies are needed

11. Applicable standards

SDS 1.2 Dental implants meet all requirements of the applicable standards listed in the table below.

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 2016-10-15 titanium
ISO 13356	Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015); German version EN 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); German version EN ISO 11137-1:2015
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 SDS1.2 dental implant system with the included components is 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 SDS1.2 dental implant system is substantially equivalent to the predicate devices.