November 6, 2018

TAV Medical Ltd.
Revital Shabtai
General Manager - Dental Division
Dora Industrial Park, P.O. Box 88
Shlomi, 2283202
ISRAEL

Re: K172668
Trade/Device Name: W Zirconia Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 9, 2018
Received: October 12, 2018

Dear Revital Shabtai:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172668

Device Name
W Zirconia Implants

Indications for Use *(Describe)*
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.

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: K172668

5.1 Applicant's Name: **TAV Medical Ltd.**

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5.3 Date Prepared: November 6, 2018

5.4 Trade Name: W Zirconia Implants

5.5 Classification Name: Endosseous Dental Implant

5.6 Common Name: Endosseous Dental Implant

5.7 Medical Specialty: Dental

5.8 Product Code: DZE, NHA

5.9 Device Class: Class II

5.10 Regulation Number: 872.3640

5.11 Review Panel: Dental

5.12 Predicate Devices

TAV Medical's W Zirconia Implants include implants and abutments that are substantially equivalent to the following Predicate Devices:

Primary Predicate device

	Device Owner / Trade Name	510(k) #	Product Code
Primary Predicate	Institute Straumann AG	K151328	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment

Reference devices

	Device Owner / Trade Name	510(k) #	Product Code
Reference device	Z-Systems AG	K120793	DZE (Implant, Endosseous, Root-Form
Reference device	Z-Systems AG	K132881	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment
Reference device	Dentalpoint AG	K163043	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment
Reference device	COHO Technology Co. Ltd.	K132585	DZE (Implant, Endosseous, Root-Form
Reference device	Institute Straumann AG	K994119	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment
Reference device	TAV Medical Ltd.	K170131	DZE (Implant, Endosseous, Root-Form) & NHA (Endosseous Dental Implant Abutment

5.13 Intended use / Indication for Use

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.

5.14 Implant Description

W Zirconia Implants are suitable for one or two stage endosseous form of dental implants. One Piece and Two-Piece implants are available.

The abutments are used in conjunction with the endosseous dental implant in order to support in the prosthetic rehabilitation.

The implantation procedure can be accomplished, for the One-piece implant in a one stage and for the two piece implant in a one or two stage surgical procedures.

TAV Medical's W Zirconia Implants are composed of the following implant models:

W One Piece – monotype implant with integrated abutment.
W Two Piece –implant for screw retained Abutment.

In both implants the endosteal region is provided with a roughness with a Ra value of 2.3 µm.

The implants and abutments are tissue level designed and includes a body portion (implant body diameter 4.1 mm with a 4.8 mm platform, and implant body diameter 4.8 mm with a 6.0 mm platform) and a neck (1.8mm). The implant body portion is configured to extend into the bone and osseo-integrate with the alveolar bone. The neck should be positioned 1.8mm above the bone level.

TAV Medical's W Zirconia Implants are made of Yttria stabilized tetragonal zirconia (Y-TZP).

Each Two piece implant is accompanied with a standard titanium cover screw.

5.15 Titanium Abutments for the W Two Piece Zirconia Implant

Dental implants abutments are intended for used as an adapter between the implant and the crown. The abutments are characterized by distinct geometrically features: Height/length, angle and diameter. Abutment device refers to the fixture that is connected to the implant. The crown is then built on the abutment for final restoration.

TAV Medical titanium abutments and abutment screws, as in other available in the market dental abutments are dental components composed of titanium (Ti6AL4V ELI).

The abutments are supplied non-sterile to be sterilized by the physician before use according to the instruction for use.

TAV Medical abutments are intended to be connected to W Zirconia implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

The abutments are available in different sizes and angles to fit individual patient needs.
The appropriate abutment type is selected in relation to the tooth position for the proposed implant. Various abutments types are available as follows:

5.16 PEEK Healing Caps

Healing caps are screwed into the implant to protect the inner configuration of the implant during the healing phase in cases of transmucosal healing protocol. TAV Medical healing caps are indicated to be placed in patients' mouth at the end of TAV Medical implant placement for a maximum of 180 days.

Healing caps are used during healing phase only and do not support a restoration.
The components are supplied non-sterile to be sterilized by the physician before use according to the instruction for use.

TAV Medical Supply Healing caps in different categories:

1. Healing caps for W One Piece Zirconia implant

2. Healing caps for W Two Piece Zirconia implant – designed to protect the inner configuration of the implant during the healing phase in cases of transmucosal healing protocol.

5.17 Substantial Equivalence discussion - Implants

The proposed W Zirconia Implants have similar indications for use, technological characteristics, mode of operation and performance specifications as its predicate devices listed .

Both the proposed and predicate devices function in the same manner providing support for prosthetic devices in the upper or lower jaw.

The following tables summarize the equivalence comparison between TAV Medical's W Zirconia Implants systems and its predicates.

5.18 Substantial Equivalence Table - Implants

Owner:	**TAV Medical Ltd.**	**Institute Straumann AG**	**Z-Systems AG**	**Z-Systems AG**	**Dental Point AG**	**COHO Technology Co. Ltd.**	**TAV Medical Ltd.**
	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**
Trade Name	W One Piece Zirconia implant	Pure Ceramic Implants	Previous name Z-Look3 Evo SLM curent name Z5M			Zi-Bone Ceramic Dental Implant System	
	W Two Piece Zirconia Implant	Pure Ceramic Implants		Z5c	Zeramex P6	Zi-Bone Ceramic Dental Implant System	Dental Implant System
K#	K172668	Cleared under: K151328	Cleared under: K120793	Cleared under: K132881	Cleared under: K163043	Cleared under: K132585	Cleared under: K170131
Product Code	DZE & NHA	DZE & NHA	DZE	DZE & NHA	DZE	DZE	DZE & NHA
Manufacturer	TAV Medical Ltd.	Institute Straumann AG	Z-Systems AG	Z-Systems AG	Dental Point AG	COHO Technology Co. Ltd.	TAV Medical Ltd.

Owner:	TAV Medical Ltd.	Institute Straumann AG	Z-Systems AG	Z-Systems AG	Dental Point AG	COHO Technology Co. Ltd.	TAV Medical Ltd.
	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**
Device Description	TAV Medical's W Zirconia implants are made from Yttria stabilized tetragonal zirconia (Y-TZP). Cover screws are manufactured from Titanium Alloy TI 6AL 4V ELI. TAV Medical's W Zirconia implants are tissue level one piece and two piece implant. The endosteal region has rough surface.	Zirconia implant features a monotype design where the ceramic abutment for final restoration is already built in	zirconia (Y-TZP). The Z-Look3 Eva SLM surface is grit blasted with medical grade A1203 and laser modified. Implants are available in three diameters (3.6, 4.0 and 5.0 mm) and four lengths (8, 10, 11.5 and 13 mm). Z-Look3 Eva SLM implants are designed for single or multiple tooth restorations. Z-Look3 Evo SLM implants are a modification to Z-Look3 implants. The laser modified surface has been added to increase surface roughness and, therefore, the surface area available for contact with bone.	Z5c is a two piece, root-form, threaded implant and abutment system made from yttria-stabilized-zirconia (Y-TZP). The Z5c implant endosseous surface is grit blasted and laser modified. The Z5c implant and corresponding abutment are bonded together using a self-adhesive resin cement. The Z5c implant system is designed for single or multiple tooth restorations. Z5c implants are provided in two endosseous diameters (4.0 and 5.0mm) and each diameter is provided in three lengths (8, 10, and 12mm). Z5c abutments are provided in two designs, straight and angled 15°.	The Zeramex® P6 Dental implant System is an endosseous dental implant/ abutment system including various sizes of endosseous two piece dental implants, abutments and accessories. The Zeramex® P6 implants may be restored with cement retained abutments or screw retained abutments, depending on the dentist's preference The Zeramex® P6 implants are placed using the Zeramex® P6 surgical tools.	Zibone® Ceramic (Zirconia) Dental Implants are threaded; root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices. Implants for surgery-ceramic materials based on yttria-stablized tetragonal ziconia (Y-TZP). The implant has a one-piece design (both implant and abutment).	

Owner:	TAV Medical Ltd.	Institute Straumann AG	Z-Systems AG	Z-Systems AG	Dental Point AG	COHO Technology Co. Ltd.	TAV Medical Ltd.
	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**
Intended Use/ Indications for Use	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.	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only. The Straumann® PURE Ceramic Implant Protective Cap is intended to protect the Straumann® PURE Ceramic Implant (Monotype) during the healing phase after implant placement for up to 6 months. Temporary copings are intended to serve as a base for temporary crown or bridge restoration for the Straumann® PURE Ceramic Implant (Monotype) for up to 30 days.	Z-Look3 Evo SLM implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z-Look3 Evo SLM implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.	Z5c implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5c implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them. Z5c implants are intended for delayed loading.	The Zeramex P6 Dental Implant Systems is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth,in order to restore aesthetics and chewing function. The Zeramex P6 Dental Implant System can be used for single or multiple unit restorations. The Zeramex P6 implants are intended for delayed loading. The Zeramex P6 Dental Implants are specially indicated for patients with metal allergies /intolerances and chronic illnesses due to metal allergies/ intolerances. The Zeramex P6 (Ø3.3) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.	Zibone one-piece ceramic dental implants are indicated for implantation into the upper or lower jaw to replace missing teeth. They are indicated for (delayed or immediate) loading once primary stability has been achieved.	

Owner:	**TAV Medical Ltd.**	**Institute Straumann AG**	**Z-Systems AG**	**Z-Systems AG**	**Dental Point AG**	**COHO Technology Co. Ltd.**	**TAV Medical Ltd.**
	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**
Material	yttria-stabilized zirconia (Y-TZP)	yttria-stabilized zirconia (Y-TZP)	yttria-stabilized zirconia (Y-TZP)	yttria-stabilized zirconia (Y-TZP)	Aluminum Toughened Zirconia ATZ	yttria-stabilized zirconia (Y-TZP)	
Manufacturing Technology	CIM: Ceramic injection molding	Turning	Turning	Turning	Turning	CIM: Ceramic injection molding	
Body Diameter (mm)	W One Piece Zirconia implant 4.1, 4.8	3.3, 4.1	3.6, 4.0, 5.0			3.6, 4.0, 5.0	
	W two Piece Zirconia implant 4.1, 4.8	3.3, 4.1		4.0, 5.0	3.3, 4.1, 4.8		
Threaded Length (mm)	W one piece Zirconia implant 8, 10, 12	8, 10, 12, 14	8, 10, 11.5, 13			8, 10, 11.5, 13 & 14.5	
	W two piece Zirconia implant 8, 10 ,12	8, 10, 12, 14		8, 10, 12	8, 10, 12		
Design	W One Piece Zirconia implant	One Piece	One Piece			One Piece	
	W Two Piece Zirconia Implant	One Piece		2 Piece	2 Piece		
Prosthetic Connection	W One Piece Zirconia implant	One Piece	One Piece			One Piece	
	W Two Piece Zirconia Implant: internal Hex screw retained	One Piece		Internal Connection cement Abutment	External Hex Flat connection, screw retained abutment		
Surface Topography	roughness	-roughness	roughness	-roughness	roughness	roughness	

Owner:	TAV Medical Ltd.	Institute Straumann AG	Z-Systems AG	Z-Systems AG	Dental Point AG	COHO Technology Co. Ltd.	TAV Medical Ltd.
	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Reference Device**
Sterilization Method	Gamma Irradiation	Plasma	Steam	Steam	Steam	Moisture Heat	Gamma Irradiation
Sterile Package	Sterile barrier sealed tube	Sterile barrier sealed blister	Sterile barrier sealed blister	Sterile barrier sealed blister	Sterile barrier sealed blister	Sterile barrier sealed blister	Sterile barrier sealed tube
Intended Use Environment	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	
Abutments	Straight and Angulated	Straight and Angulated	Straight (integrated)	Straight and Angulated	Straight and Angulated	Straight (integrated)	

Substantial Equivalence Discussion: as demonstrated in the above table the TAV Medical's subject device is equivalent to the selected predicate device.

The subject device is similar to the predicate devices in terms of indications for used, technological characteristics and design key elements (including surface treatment, dimensions, connection types, etc.).

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

In terms of indications for use, the Ø3.3 mm was excluded from TAV Medical indications for use phrasing since such product diameter does not exist in our submission. This exclusion is not significant because it narrows the statement.

The protective caps intended for use of up to 6 months in the primary predicate device are intended to be used for a similar period of time of up to 180 days in our zirconia implant system and are referred to as healing caps.

The temporary caps intended for use of up to 30 days in the primary predicate device are intended to be used for up to 180 days in our zirconia implant as our temporary caps are manufactured from PEEK. We believe that this is not a significate difference as well, since the PEEK material used by TAV Medical is already cleared for 180 days in our previous 510(k) # K170131.

In terms of production technology, while TAV Medical utilizes CIM, ceramic injection molding, the primary predicate is manufactured using turning technology. This difference is bridged by the reference predicate device cleared under 510(k) K132585 manufactured using the CIM technology.

In terms of the outer diameter dimensions of the W one piece zirconia implant the slight dimensional differences are covered by the reference predicate devices cleared under 510(k) K120793 and K132585.
For the W two-piece zirconia implant the slight dimensional differences are covered by the reference devices cleared under 510(k) K132881 and K163043.
In terms of the design feature and prosthetic connections type for the W two-piece zirconia implant, the primary predicate is a one piece implant and therefore the two-piece reference devices cleared under 510(k) K132881 and K163043 bridge the difference. The subject device connection type is an internal Hex screw retained connection which differs from the primary predicate device. The predicate devices K132881 and K163043 contain an internal connection type that covers the screw retained feature.
In terms of sterilization methods, W Zirconia Implants are sterilized using Gamma irradiation. Gamma irradiation is a common sterilization method that was fully validated by TAV Medical in order to assure sterilization assurance level (SAL) of at least 10^{-6}.

TAV Medical W Zirconia Implants are packed in sterile barrier sealed tube while the primary predicate device is packed in a sterile barrier sealed blister. This difference was bridged using TAV Medical's packaging system cleared under 510(k) K170131.
It was concluded that TAV Medical's subject device fulfills the criteria for substantial equivalence.

5.19 Substantial Equivalence - Abutments

TAV Medical abutments, as its predicate devices abutments, are intended to be placed into implants of different types, diameter, lengths and platforms to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.
The following table summarizes the equivalence of TAV Medical abutments to its predicate devices:

PEEK Healing Cap for W One Piece Zirconia Implant

	TAV Medical Ltd.	Institute Straumann AG	TAV Medical Ltd.
	Subject Device	**Primary Predicate Device**	**Reference Device**
Product Code	DZE, NHA	DZE, NHA	DZE, NHA
K#	K172668	K151328	K170131
Product Name	PEEK Healing Cap for W One Piece Zirconia Implant	PURE Ceramic Protective Caps	PEEK Abutments
Product Description	Protect the implant during the healing phase up to 180 days.	Protect the Implant during the healing phase after implant placement for up to 6 months.	N/A
Material	PEEK	PEEK	PEEK
Diameter (mm)	4.1, 4.8	3.3, 4.1	
Height (mm)	5	4, 5.5	
Angle (°)	0	0	0
sterility	Non Sterile	Non Sterile	Non Sterile

Substantial Equivalence Discussion: The minor differences in the products diameter or height do not raise any performance differences due to the similarity of TAV Medical's PEEK healing cap to its predicate device design and range. In addition, the PEEK components which are manufactured in the same facility using the same manufacturing processes as used for the current submission components, have been previously cleared under K170131.

Therefore, it may be concluded that TAV Medical's PEEK Healing Caps for W One Piece Zirconia Implants and its predicates share the same intended use and technological characteristics and therefore are substantially equivalent.

PEEK Temporary Caps for W One Piece Zirconia Implant

Feature	TAV Medical Ltd.	Institute Straumann AG	TAV Medical Ltd.
	Subject Device	Primary Predicate Device	Reference Device
Product Code	DZE, NHA	DZE, NHA	DZE, NHA
K#	K172668	K151328	K170131
Product Name	Temporary Caps	PURE Ceramic Temporary Copings	PEEK Abutments
Product Description	Serves as a basis for temporary restoration for crown or bridge. Up to 180 days	Serves as a base for temporary crown or bridge restoration. Up to 30 days	
Material	PEEK	polymethylmethacrylate (PMMA)	PEEK
Diameter (mm)	4.1, 4.8	3.3, 4.1	
Angle (°)	0	0	0
sterility	Non Sterile	Non Sterile	Non Sterile

Substantial Equivalence Discussion: The temporary caps intended for use of up to 30 days in the primary predicate device are intended to be used for up to 180 days in our zirconia implant as our temporary caps are manufactured from PEEK. the PEEK components which are manufactured in the same facility using the same manufacturing processes as used for the current submission components, have been previously cleared under K170131 for 180 days.

The minor differences in the products diameter do not raise any performance differences due to the similarity of TAV Medical's PEEK temporary cap to its predicate device design and range. Therefore, it may be concluded that TAV Medical's PEEK temporary caps for W One Piece Zirconia Implants and its predicates share the same intended use and technological characteristics and therefore are substantially equivalent.

PEEK Healing Cap for W Two Piece Zirconia Implant

Feature	TAV Medical Ltd.	Z-Systems AG	Dental Point AG	TAV Medical Ltd.
	Subject Device	Primary Predicate Device	Reference Device	Reference Device
Product Code	NHA	NHA	NHA	DZE, NHA
K#	K172668	K132881	K163043	K170131
Product Name	PEEK Healing Cap for Zirconia Implant	Healing caps / Gingiva former	Healing caps / Gingiva former	PEEK Abutments
Product Description	Used to allow the gingiva to heal	Used to allow the gingiva to heal	Used to allow the gingiva to heal	
Material	PEEK+ Titanium connecting screw	PEEK	PEEK	PEEK
Diameter (mm)	4.8, 6	4, 5	6	
Height (mm)	1, 2 ,3, 4mm	0.6, 2.8, 3.3mm	0.5, 3, 4mm	
Angle (°)	0	0	0	
sterility	Non Sterile	Non Sterile	Non Sterile	Non Sterile

Substantial Equivalence Discussion: as can be seen in the above comparison table all TAV Medical's subject device diameter and height dimensions are within the range of both, primary and reference predicate devices. In addition, the PEEK components which are manufactured in the same facility using the same manufacturing processes as used for the current submission components, have been previously cleared under K170131. In addition, the TAV Medical's PEEK Healing Caps are intended to be connected with a titanium connecting screw rather than PEEK cemented as the primary predicate, however the method of connecting prosthetic device to an implant using a titanium screw is well established in the dental implant market and does not affect the performances of the product.

Therefore, it may be concluded that TAV Medical's PEEK Healing Caps and its predicates share the same intended use and technological characteristics and therefore are substantially equivalent.

Titanium Abutments, Straight & Angulated

Feature	TAV Medical Ltd.	Institute Straumann AG
	Subject Device	**Primary Predicate Device**
Product Code	NHA	DZE (cleared by the FDA as abutment on March 17 2000)
K#	K172668	K994119
Product Name	Titanium Abutments	RN synOcta® Abutment
Product Description	Screw Retained Titanium Abutments	Screw Retained Titanium Abutments
Material	TI-6AL4V ELI Anodized	Titanium
Diameter (mm)	4.8	4.8
Length (mm)	5.0, 6.0	5.5, 5.7, 6.7
Angle (°)	0, 5, 10, 15	0, 15, 20
Sterility	Non Sterile	Non Sterile

Substantial Equivalence Discussion: TAV Medical Titanium Abutments and its predicates share the same intended use and technological characteristics and therefore are substantially equivalent.

Summary

In summary, the differences between the subject device and the predicate devices were evaluated and tested and do not raise new concerns.

5.20 Non clinical testing

5.19.1 Biocompatibility

Testing and evaluation for materials biocompatibility according to ISO 10993-1 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.” Requirements and the corresponding FDA guidance, “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 16, 2016” were performed in order to demonstrate the biocompatibility of the system.

5.19.2 Sterilization validation and shelf life

Implants sterilization validation was conducted in compliance with ANSI/AAMI/ISO 11137 in order to ensure the sterility of TAV Medical’s W Zirconia Implants.
Abutments steam heat sterilization validation was performed in compliance to the FDA requirements’ and conformance to ANSI IAAMI/ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Validation results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Accelerated aging have been applied on the final packaging and is followed by real time aging validating implants packaging to one year of shelf life.

5.19.3 Performance Testing

TAV Medical's W Zirconia Implants performance bench testing was specified through the application of a risk analysis driven process. As part of this process the forces and operating conditions the device is exposed to during the procedure were evaluated and analyzed, and as a result the required bench tests were derived.

In addition, applicable FDA guidance (and other standards) was reviewed for determining required bench testing. Bench testing was performed to demonstrate that the W Zirconia Implants meet existing acceptance criteria similar to other predicate devices.

Descriptive information, laboratory bench testing, and biocompatibility testing are provided to demonstrate W Zirconia Implants meets its design specifications, performs as intended.

Specifically, the system was evaluated through design verification testing including the following: Implant to abutment compatibility testing, Static and dynamic fatigue testing according to ISO 14801, Surface finish analysis & Zirconia Material wear testing

The non-clinical testing results showed that the proposed implant system meet the device requirements and are equivalent to the predicate devices. The subject devices and the predicate device have the same intended use and technological characteristics.

5.20 Animal Testing

No Animal studies were performed.

5.21 Clinical testing

No clinical studies were performed.

5.22 The System complies with the following standards:

#	Standard #	Standard Title
1.	ISO 14971:2007	Medical devices -- Application of risk management to medical devices
2.	ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
3.	ISO 11137-1:2006	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (
4.	AAMI TIR 33:2005	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method
5.	ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
6.	ISO 14801:2016	Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants
7.	ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
8.	ISO 15223-1: 2016	Symbols to be used with medical device labels, labelling, and information to be supplied: Part 1: General requirements

#	Standard #	Standard Title
9.	ISO 13356: 2015	Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)
10.	ASTM D999-08 (2015)	Standard Test Methods for Vibration Testing of Shipping Containers
11.	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
12.	ASTM D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
13.	ASTM D4991-07 (2015)	Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method
14.	ASTM D5276-98 (2017)	Standard Test Method for Drop Test of Loaded Containers by Free Fall
15.	ASTM F1929-15	Standard Test Method for Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration
16.	ISO 11607-1:2006	Packaging for terminally sterilized medical devices-Part 1:Requirements for materials, sterile barrier systems and packaging systems
17.	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

5.23 Summary

Based on the substantial equivalence discussion, performance testing results and compliance to applicable standards, the W Zirconia Implants is substantially equivalent to its predicates.