October 29, 2019

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

Re: K192053
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: July 31, 2019
Received: July 31, 2019

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/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
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

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)*

K192053

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.

The ø3.6mm reduced diameter implants are recommended for central and lateral incisors only.

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
TAV Medical Ltd. – W Zirconia Implants

1. Submitter Information

Submitter's Name:	TAV Medical Ltd. Dora Industrial Park P.O.B 88, Shlomi 2283202 Israel
Phone Number:	+972 (4) 9808615/503
Fax Number:	+972 (4) 9808356
Contact Person**:**	Mrs. Revital Shabtai E-mail: revitals@tavmedical.com
Date:	October 29, 2019

2. Device

Trade Name:	W Zirconia Implants
Common Name:	Endosseous Dental Implant Endosseous Dental Implant Abutment
Classification Name:	21 CFR 872.3640
Device Class:	Class ll
Primary Product Code:	DZE
Secondary Product Code:	NHA

3. Predicate Devices

Primary Predicate:	K172668 W Zirconia Implants
Reference Devices:	K151328 Pure Ceramic Implants
	K180477 Straumann Pure Ceramic Implants

4. Device Description

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

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

The implants are tissue level designed and includes a body portion 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). This material conforms with ISO 13356:2015 standard for Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).

The Titanium abutments are going through anodizing process using an electrolytic process that adjusts the oxide level of the metal surface. This adjustment changes the spectrum of light, resulting in perceived color. By controlling the surface oxide level, an entire range of colors can be achieved.

The Subject Device includes the following dimensions:

W One-Piece implants: Diameter of 3.6mm for lengths of 8mm, 10mm, 12mm and 14mm and;
Diameters of 4.1mm and 4.8mm for length of 14mm.

W Two-Piece implants: Diameters of 4.1mm and 4.8mm for lengths of 8mm, 10mm, 12mm and 14mm.

Cover Screw are screwed into the implant to protect the inner configuration of the implant during the healing phase in cases of submucosal healing protocol. Cover screws are made of Titanium alloy Ti 6Al 4V ELI & Anodize and are available in diameters of 4.1mm and 4.8mm.

Titanium Healing Caps are intended to protect the 2-piece implants during the healing phase. The healing caps also support the emergence profile and keep the implant shoulder ideal for the impression phase. The healing caps are available in different geometrical features such as height and diameter. The Titanium Healing Caps manufactured from Ti 6Al 4V ELI & Anodize and are available in diameters

of 4.1mm and 4.8mm. Each diameter is provided with height dimensions of 1mm, 2mm, 3mm and 4mm.

PEEK Healing Caps are designed to protect the two-piece implant during the healing phase. The healing caps also support the emergence profile and keep the implant shoulder ideal for the impression phase. Peek healing caps are available in different geometrical features such as height and diameter and available in 2 different designs, one design for the one-piece implant and second design for the two-piece implant. Both designs are manufactured from PEEK material and are indicated to be placed in patients' mouth for a maximum duration of 180 days. The PEEK healing caps are available in diameters of 4.1mm and 4.8mm and height dimensions of 1mm, 2mm, 3mm and 4mm.

PEEK Temporary Caps serves as a basis for temporary restoration. TAV Medical temporary restoration caps available in two configurations, temporary Cap for Crown and Temporary Cap for Bridge. The caps are manufactured from PEEK material and are indicated to be placed in patients' mouth for a maximum duration of 180 days. The PEEK temporary caps are available in diameter of 3.6mm.

Titanium Abutments for the W Two Piece Zirconia Implants are intended for use as an adapter between the implant and the crown. The abutments are characterized by distinct geometrical features such as length and angulation. The titanium abutments are manufactured from ASTM F136-13 compatible Titanium Ti 6Al 4V ELI & Anodize. TAV Medical abutments are intended to be connected to 2-piece W Zirconia implants with titanium screw, to provide support for prosthetic reconstructions. The abutments are available in the following dimensions: Length of 5.0mm and 6.0mm and Angles of 0^o, 5^o, 10^o and 15^o. The 0^o serves also for bridges.

5. 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 ø3.6mm reduced diameter implants are recommended for central and lateral incisors only.

6. Technological Characteristics

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

The following abutments interacts with the two-piece implants as follows:
Cover Screw protect the inner configuration of the implant during the healing phase in cases of submucosal healing protocol.
Titanium Healing Caps Protect the implant during the healing phase, and maintain, stabilize and form the soft tissue during the healing process.
PEEK Healing Caps Protect the implant during the healing phase up to 180 days, and maintain, stabilize and form the soft tissue during the healing process.
PEEK Temporary Caps Serves as a basis for temporary restoration for crown or bridge. Up to 180 days.
Titanium Abutments for the W Two Piece Zirconia Implants are intended for use as an adapter between the implant and the crown.

The following tables summarize the equivalence comparison between TAV Medical's W Zirconia Implants systems and its primary predicate and reference devices:

Implants:

Owner: / Feature	TAV Medical Ltd.	TAV Medical Ltd.	Institute Straumann AG	Institute Straumann AG
	Subject Device	Primary Predicate Device	Reference Device	Reference Device
Trade Name	W One Piece Zirconia implant	W One Piece Zirconia implant	Pure Ceramic Implants	--
	W Two Piece Zirconia Implant	W Two Piece Zirconia Implant	--	Straumann Pure Ceramic Implant systems
510(k) Number	K192053	Cleared under: K172668	Cleared under: K151328	Cleared under: K180477
Product Code	Primary: DZE Secondary: NHA	Primary: DZE Secondary: NHA	Primary: DZE Secondary: NHA	Primary: DZE Secondary: NHA
Manufacturer	TAV Medical Ltd.	TAV Medical Ltd.	Institute Straumann AG	Institute Straumann AG

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 ø3.6 mm reduced diameter implants are recommended for central and lateral incisors 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.	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.	Straumann PURE Ceramic Implant: The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding compnents. Closure and healing caps: Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months. Temporary Abutments: The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary

Owner: / Feature	TAV Medical Ltd.	TAV Medical Ltd.	Institute Straumann AG	Institute Straumann AG
	Subject Device	Primary Predicate Device	Reference Device	Reference Device
				Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days. CI RD Straumann PUREbase Abutments: CI RD Straumann PUREbase abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.
Material	yttria-stabilized zirconia (Y-TZP)	yttria-stabilized zirconia (Y-TZP)	yttria-stabilized zirconia (Y-TZP)	yttria-stabilized zirconia (Y-TZP)
Manufacturing Technology	CIM: Ceramic injection molding	CIM: Ceramic injection molding	Turning	Turning
Diameter (mm)	W two Piece Zirconia implant Ø 4.1, 4.8	W two Piece Zirconia implant Ø 4.1, 4.8	--	Ø 4.1
	W one piece Zirconia implant Ø 3.6	W One Piece Zirconia implant Ø 4.1, 4.8	Ø 3.3, 4.1	--
Length (mm)	W two piece Zirconia implant 8, 10, 12, 14	W two piece Zirconia implant 8, 10 ,12	--	8, 10, 12, 14

Owner: / Feature	TAV Medical Ltd.	TAV Medical Ltd.	Institute Straumann AG	Institute Straumann AG
	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	W One Piece Zirconia implant 8, 10, 12, 14	W One Piece Zirconia implant 8, 10 ,12	One Piece 8, 10, 12, 14	--
Design	W Two Piece Zirconia Implant	W Two Piece Zirconia Implant	--	Two-piece
	W One Piece Zirconia implant	W One Piece Zirconia implant	One Piece	--
Prosthetic Connection	W Two Piece Zirconia Implant: screw retained	W Two Piece Zirconia Implant: Internal hex screw retained	--	screw retained
Surface Topography	macro- and micro-roughness	macro- and micro-roughness	macro- and micro-roughness	macro- and micro-roughness
Accessories	Surgical Instruments	Surgical Instruments	Surgical Instruments	Surgical Instruments
Sterilization Method	Gamma Irradiation	Gamma Irradiation	H2O2 plasma	Ethylene Oxide
Intended Use Environment	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting
Abutments	Straight and Angulated	Straight and Angulated	Straight	Straight and Angulated

Prosthetics

PEEK Healing Cap for W One Piece Zirconia Implant

Feature	TAV Medical Subject Device	TAV Medical Primary Predicate Device	Institute Straumann AG Reference Predicate Device
Product Code	NHA	NHA	NHA
K#	K192053	K172668	K151328
Product Name	PEEK Healing Cap for W One-piece Zirconia Implant	PEEK Healing Cap for W One-piece Zirconia Implant	PURE Ceramic Protective Caps
Product Description	Protect the implant during the healing phase up to 180 days.	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.
Material	PEEK	PEEK	PEEK
Diameter (mm)	3.6	4.1, 4.8	3.3, 4.1
Height (mm)	5	5	4, 5.5
Angle (°)	0° (Straight)	0° (Straight)	0° (Straight)
sterility	Non-Sterile	Non-Sterile	Non-Sterile

PEEK Temporary Caps for W One-piece Zirconia Implant

Feature	TAV Medical Subject Device	TAV Medical Primary Predicate Device	Institute Straumann AG Reference Predicate Device
Product Code	NHA	NHA	NHA
K#	K192053	K172668	K151328
Product Name	Temporary Caps	Temporary Caps	PURE Ceramic Temporary Copings
Feature	**TAV Medical Subject Device**	**TAV Medical Primary Predicate Device**	**Institute Straumann AG Reference Predicate Device**
Product Description	Serves as a basis for temporary restoration for crown or bridge. Up to 180 days	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	PEEK	polymethylmethacrylate (PMMA)
Diameter (mm)	3.6	4.1, 4.8	3.3, 4.1
Angle (°)	0° (Straight)	0° (Straight)	0° (Straight)
sterility	Non-Sterile	Non-Sterile	Non-Sterile

PEEK Healing Cap for W Two Piece Zirconia Implant

Feature	TAV Medical Subject Device	TAV Medical Primary Predicate Device
Product Code	NHA	NHA
K#	K192053	K172668
Product Name	PEEK Healing Cap for W Two Piece Zirconia Implant	PEEK Healing Cap for W Two Piece Zirconia Implant
Product Description	Protect the implant during the healing phase up to 180 days and maintain, stabilize and form the soft tissue during the healing process	Protect the implant during the healing phase up to 180 days and maintain, stabilize and form the soft tissue during the healing process
Material	PEEK + Titanium connecting screw	PEEK + Titanium connecting screw
Diameter (mm)	5, 6.2	4.8, 6
Height (mm)	1, 2, 3, 4	1, 2, 3, 4
Angle (°)	0° (Straight)	0° (Straight)
sterility	Non-Sterile	Non-Sterile

Titanium Healing Cap for W Two Piece Zirconia Implant

Feature		TAV Medical Subject Device	TAV Medical Primary Predicate Device	Institute Straumann AG Reference Predicate Device
Product Code		NHA	NHA	NHA
K#		K192053	K172668	K180477
Product Name		Titanium Healing Cap for W Two Piece Zirconia Implant	PEEK Healing Cap for W Two Piece Zirconia Implant	Straumann PURE ceramic Implant System Closure and Healing Caps
Product Description		protect the implant during the healing phase and maintain, stabilize and form the soft tissue during the healing process	Protect the implant during the healing phase up to 180 days.	Protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.
Material		Titanium	PEEK+ Titanium connecting screw	Titanium
Diameter (mm)		5, 6.2	4.8, 6	4.8, 5.2
Height (mm)		1, 2, 3, 4mm	1, 2, 3, 4mm	2, 3 mm
Angle (°)		0	0	0
sterility		Non-Sterile	Non-Sterile	sterile

Titanium Abutments, Straight & Angulated

Feature	TAV Medical Subject Device	TAV Medical Primary Predicate Device
Product Code	NHA	NHA
K#	K192053	K172668
Product Name	Titanium Abutments	Titanium Abutments
Product Description	Screw Retained Titanium Abutments	Screw Retained Titanium Abutments
Material	TI-6AL4V ELI Anodized	TI-6AL4V ELI Anodized
Diameter (mm)	4.8	4.8
Length (mm)	5.0, 6.0	5.0, 6.0
Angle (°)	0, 5, 10, 15	0, 5, 10, 15
Sterility	Non-Sterile	Non-Sterile

7. Performance Testing data

The following performance tests have been provided to demonstrate that the W Zirconia Implant system is substantially equivalent to the identified primary and reference predicate devices:

Biocompatibility testing

The subject devices are manufactured using identical manufacturing methods, in the same manufacturing facility and environment, and using the exact same raw material as the primary predicate device, therefore no new issues regarding biocompatibility according to ISO 10993-1 were raised.

For these reasons, no additional tests have been conducted, as the biocompatibility reports as well as the additional technical documentation were fully submitted within our previously cleared 510(k) K172668. It was concluded that the materials biocompatibility was already established and that no additional tests or documentation are required for the purpose of this submission.
The standards and guidance documents used to establish the biocompatibility were:

- FDA Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk

management process", dated June 16, 2016.

- ISO 10993-1:2018 for Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 for Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.

Sterilization and Shelf Life

Implants sterilization validation was leveraged from TAV Medical primary predicate device cleared under 510(k) number K172668. The tests were conducted in accordance with ANSI/AAMI/ISO 11137-2:2013 for Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose 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 Guidance for Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (January 21, 2016) and in conformance to ANSI IAAMI/ISO 17665-1:2006 for 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.

Mechanical testing

TAV Medical performed the required performance testing for the W Zirconia Implants according to the FDA guidance document for Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments (May 2004) and ISO 14801:2016 for Dentistry-Implants- Dynamic fatigue test for endosseous dental implants. The results indicated the subject devices are substantially equivalent to the primary predicate device.

Bench tests were conducted on the subject device after fatigue testing to assess the implant-to-abutment connection comparison in order to evaluate the wear of the surfaces of the implant body, abutment and fixation screw and screw loosening. The data produced concluded of comparable behavior of the subject device to the

reference devices in terms of wear on the implant-to-abutment connection and screw loosening.

8. Conclusion

TAV Medical's W Zirconia Implants have the same intended use, indications for use, mode of operation, materials, manufacturing technology and body contact as the predicate devices. The documentation submitted in this premarket notification demonstrates that the subject device has been determined to be substantially equivalent to the identified primary and reference predicate devices.