February 10, 2018

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

Re: K170131
Trade/Device Name: TAV Medical Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 1, 2018
Received: January 4, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170131

Device Name

TAV Medical Dental Implant System

Indications for Use *(Describe)*

TAV Medical Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or 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 also 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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TAVMedical
PRECISION. PASSION. PARTNERSHIP

510(K) Summary for TAV Medical Dental Implant System

510(K) Number: K170131

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Date Prepared: 10 February 2018

Trade Name: TAV Medical Dental Implant System

Classification Name: Implant, Endosseous, Root-Form

Medical Specialty: Dental

Product Code: DZE (primary), NHA (secondary)

Device Class: Class II

Regulation Number: Primary 872.3640

Review Panel: Dental

Predicate Devices

TAV Medical Dental Implant System including Implants and Abutments are substantially equivalent to the following Predicate Devices, divided to primary and reference devices:

Device Owner / Trade name	Primary Predicate Device 510(k) number	Product code
MIS Dental Implant System	K040807	DZE (primary) and NHA (secondary)

The following devices are used as reference devices:

Device Owner / Trade name	Reference device 510(k) number	Product code
MIS Dental Implant System	K112162	DZE (primary) and NHA (secondary)
Hahn Tapered Implant System	K143353	DZE
Noris Medical Dental Implant System	K140440	NHA
SGS Dental Implants System	K133362	NHA
AB DENTAL Devices Ltd.	K132125	NHA
Implant Direct	K143011	NHA
Ditron Dental Ltd.	K140728	DZE

Indications for Use

TAV Medical Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or 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 also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Implant Description

TAV Medical Dental Implant System is a two piece dental implant system for one stage or two stage surgical implantation of dental implant provided with cover screw and supported by a compatible abutment systems and surgical instruments.

The implant is fabricated from a medical grade titanium alloy 6Al 4V ELI, according to ASTM F136. TAV Medical implant includes a body portion and a collar. The body portion is configured to extend into and Osseo integrate with the alveolar bone. The top surface of the collar lies flush with the crest of the jawbone bone. TAV Medical abutment lies on the top surface and extends through the soft tissue, which lies above the alveolar bone. The abutment supports the final prostheses.

TAV Medical implants include the following brands:

Silhouette

A Cylindrical-apically tapered screw type implant. The implant has a self-tapping design and a progressive thread. The Silhouette internal & external profile varies depending on the implant length. The internal core of the implant has a tapered shape. Silhouette implants are designed with:

- Platform switching design over the implant top geometry.
- Implant outer surface achieved by sand blasting and acid etching processes
- Cylindrical Implant Body in its apical region
- Self-Tapping design
- The implant is recommended for bone types: D1, D2 and D3.
- The implants are suitable for both one and two stage implant procedures.

Silhouette implant is designed in two platforms:

Narrow Platform (NP)

- Internal Hex Connection 2.41mm
- Available in the following dimensions:
  Diameter: 3.3mm
  Lengths: 10mm, 11.5mm, 13mm and 16mm

Standard Platform (SP):

- Internal Hexagon for anti-rotation 2.44mm
- available in the following dimensions:
  Diameters: 3.75mm, 4.2mm, 5mm, and 6mm
  Lengths: 8mm, 10mm, 11.5mm, 13mm and 16mm

Sirius

TAV Medical Sirius implants has a tapered apex with three cutting notches which makes the implant's rough surface extends from bottom to the top of the implant. The internal core of the implant has a tapered shape. Sirius implants are designed with:

- Platform switching design on the implant top geometry
- Additional two starts on the coronal region
- Deep micro thread at the coronal region
- Implant outer surface achieved by sand blasting and acid etching
- Self-Tapping design
- The implant is recommended for bone types: D2, D3 and D4.
- Apically tapered implant body
- The implants are suitable for both one and two stage implant procedures.

Sirius implant is designed in two platforms:

Narrow Platform (NP):

- Internal Hex Connection 2.41mm
- available in the following dimensions:
  Diameter: 3.3mm
  Lengths: 10mm, 11.5mm, 13mm and 16mm

Standard Platform (SP):

- Internal Hexagon for anti-rotation 2.44mm
- available in the following dimensions:
  Diameters: 3.75mm, 4.2mm, 5mm, and 6mm
  Lengths: 8mm, 10mm, 11.5mm, 13mm and 16mm

iCone

Conical Connection implants which merges cylindrical body with a conical connection. iCone implants are available in a versatile range of diameters and lengths and in two platforms, Standard and Wide platforms that are color coded for easy identification. The implants are suitable for both one and two stage implant procedures. iCone implants are designed with:

- 11° cone at the interior of the implant
- Internal Hexagon – features 6 indexing positions
- Platform switching design
- Micro threads in top coronal section
- Double Thread Design
- The implant is recommended for bone types: D1, D2 and D3.
- Implant outer surface achieved by sand blasting and acid etching

iCone implant is designed in two platforms:

Standard Platform (SP):

- Internal Hex Connection 2.10mm
- Available in the following dimensions:
  Diameters: 3.75mm and 4.2mm
  Lengths: 8mm, 10mm, 11.5mm, 13mm and 16mm

Wide Platform (WP):

- Internal Hexagon for anti-rotation 2.50mm
- Available in the following dimensions:
  Diameters: 4.5mm and 5mm.
  Lengths: 9mm, 11.5mm, 13mm and 16mm.

Abutments Description

TAV Medical Abutments are intended for used as an adapter between the implant and the crown. The abutments are characterized by four distinct geometrically features: Height/length, angle, diameter and internal/external hex lock or conical connection. Anodized Color coding is used for categorical consideration only.
TAV Medical abutments, as other available in the market of dental prosthetics are dental components composed either of titanium (Ti 6AL 4V ELI), PEEK and Yttrium Stabilized Zirconia (ZrO2). All the abutments fixation screws are composed of Ti 6AL 4V ELI.
The abutments are supplied non-sterile to be sterilized by the physician before use according to the accompanied instruction for use.
Abutment device refers to the fixture that is assembled on the implant. The crown is then built on the abutment.

The prosthetic parts are divided into 3 main categories:

- Cemented retained restorations
- Screw retained restorations
- Overdenture retained

The appropriate abutment type is selected in relation to the tooth position for the proposed implant. Various abutment types are available:

Titanium Abutments

TAV Medical Titanium Abutments are intended to be placed into TAV Medical implants of different types, diameter, lengths and platforms to provide support for prosthetic reconstructions such as crowns and bridges.

Temporary Esthetic PEEK Abutments

TAV Medical temporary PEEK abutments are intended to be used with TAV Medical Implants to provide support for individual temporary crowns and are for use of a maximum duration of 180 days.

Ball attachment

The ball attachment system is intended to secure a removable prosthesis in a complete or partial restoration by endosseous implants in the mandible or in the maxilla. The ball attachment includes a metal housing and retention caps offering retention for every individual situation. The ball attachments are made of full Titanium.

Locker overdenture

The Locker, commonly known in the market as "Locator™", is a Zirconia (ZrO2) overdenture attachment system designed for use with dentures retained in whole or in parts by endosseous implants in the mandible or in the maxilla. The locker includes a titanium denture cap and retentive caps with customizable levels of retention for multi-unit restorations in full overdentures. The locker is supplied made out fully from zirconia or partially zirconia attached to a titanium base.

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.

Substantial Equivalence discussion

The proposed TAV Medical Dental Implant System has the same indications for use, technological characteristics, mode of operation and performance specifications as its predicates devices.

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

The following table summarizes the equivalence comparison between TAV Medical Dental Implants, its primary predicate device and its reference devices.

Substantial Equivalence Table - Implants

Feature	TAV Medical [K170131] Subject Device	MIS (K040807) primary	MIS (K112162) reference	Hahn (K143353) reference
Trade Name:	Sirius	Seven (internal hex)		Hahn Tapered Implant System
	Silhouette	M4 (internal hex)		
	iCone		Conical connection	
K#	K170131	K040807 (Internal Hex – Seven & M4)	K0112162 (Conical Connection)	K143353
Product Code	DZE	DZE	DZE	DZE
Manufacturer	TAV Medical Ltd.	MIS Implant Technologies Ltd.	MIS Implant Technologies Ltd.	Prismatik dentalcraft, inc
Device Description	**Sirius** Titanium dental implant with apically tapered body (conical shape body)	**Seven** Titanium dental implant with apically tapered body (conical shape body)		The Hahn Tapered Implant System consists of dental implants, abutments,

Feature	TAV Medical [K170131] Subject Device	MIS (K040807) primary	MIS (K112162) reference	Hahn (K143353) reference
	Silhouette Titanium implant body combines a cylindrical shape in its apical region and a conical shape in the coronal region	**M4** Titanium implant body combines a cylindrical shape in its apical region and a conical shape in the coronal region		screws, and surgical instruments.They are manufactured from Titanium alloy, grade 23. The implant is designed with an internal hex connection and a tapered body to replace one or more missing teeth.
	iCone Conical connection		Conical connection	
Indications for Use	The TAV Medical Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient chewing function. The TAV Medical Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading	The MIS Dental Implant System are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.	The MIS Dental Implant System are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate	Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Feature	TAV Medical [K170131] Subject Device	MIS (K040807) primary	MIS (K112162) reference	Hahn (K143353) reference
Material	Titanium Alloy – Ti 6AL4V ELI	Titanium Alloy – Ti 6AL4V ELI	Titanium Alloy – Ti 6AL4V ELI	Titanium Alloy – Ti 6AL4V ELI
Diameter (mm)	**Sirius & Silhouette** 3.3, 3.75, 4.2, 5, 6	**Seven & M4** 3.3, 3.75, 4.2 5		3.0, 3.5, 4.3, 5.0, and 7.0
	iCone 3.75, 4.2, 4.5 , 5		**Conical connection** 3.75, 4.2, 5	
Length(mm)	**Sirius & Silhouette** 8, 10, 11.5, 13, 16	**Seven & M4** 8, 10, 11.5, 13, 16mm		8, 10, 11.5, 13, and 16
	ICone 8, 9, 10, 11.5, 13, 16		**Conical connection implans** 8, 10, 11.5, 13, 16mm	
Prosthetic Connection	**Sirius & Silhouette** Internal Hex	**Seven & M4** Internal Hex		Internal Hex
	iCone Conical		Conical connection	
Device features	Screw type	Screw type	Screw type	Screw type
Surface treatment	**Sirius & Silhouette** Sandblasting and acid etching	**Seven & M4** Sandblasting and acid etching & anodized		Blasted with Hydroxyl Apatit
	iCone Sandblasting and acid etching & anodized		Sandblasting and acid etching & anodized	

Feature	TAV Medical [K170131] Subject Device	MIS (K040807) primary	MIS (K112162) reference	Hahn (K143353) reference
Components	TAV Medical Dental Implants System consists of one and two stage endosseous form dental implants, internal hexagonal and conical connection; cover screws and healing caps; abutment systems & superstructures; surgical instruments.	The MIS Dental Implant System consists of one and two stage implants, internal and external hexagonal, conical; cover screw and healing caps; abutment systems and suprastructures; surgical instruments.	The MIS Dental Implant System consists of one and two stage implants, internal and external hexagonal, conical; cover screw and healing caps; abutment systems and suprastructures; surgical instruments.	The implant is designed with an internal hex connection and a tapered body to replace one or more missing teeth. The Implants are design with two (2) platform connection geometries
Sterile Package	Sterile barrier tube with inner sealed sleeve	Double container sealing system	Double container sealing system	Single blister, unsealed inner holder
Sterilization method	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Intended Use Environment	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting
Abutments	Straight and angulated	Straight and angulated	Straight and angulated	Straight and angulated

Substantial equivalence discussion: As shown in the table above, TAV Medical Dental implant System is Substantial equivalent in all devices' features. The only difference is in the maximal outer diameter of the proposed device versus the maximal outer diameter of the primary predicate device. This slight difference was bridged using K143353 which was cleared with up to 7.0 mm outer diameter.
TAV Medical's single sterile package slightly differs from the primary predicate device. While the MIS dental implant system contains two tubes and sleeve, TAV Dental's packaging contains one tube and an inner sealed sleeve. This difference was bridged using K140728 which utilizes the same packaging as TAV Medical and same sealing design.

There are no additional differences, thus it was concluded that the subject dental implant system is substantially equivalent with the predicate devices.

Substantial Equivalence - Abutments

TAV Medical abutments, similarly to its predicate devices, are intended to be placed in implants of different types, diameter, lengths and platforms to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

The differences between the proposed TAV Medical Abutments and the predicate devices are minor and are reflected only in the abutments' dimensions and in the addition of the Zirconia material to some of the abutment types. These differences were tested and evaluated and no issues affecting device performances were detected. Thus it was concluded that the subject dental implant system abutments is substantially equivalent with the predicate devices

Titanium Healing Cap

Feature	TAV Medical	MIS primary	Noris Medical reference
Product Code	NHA	NHA	NHA
K#	K170131	K112162, K040807	K140440
Product Name	Titanium Healing Cap	Titanium Healing Cap	Titanium Healing Cap
Product Description	Used to allow the gingiva to heal around the Gingiva	Used to allow the gingiva to heal around the Gingiva	Used to allow the gingiva to heal around the implant
Material	Titanium Alloy +Anodize	Titanium Alloy +Anodize	Titanium Alloy
Diameter (mm)	3.8, 4, 4.5, 4.7, 5, 5.5, 6.5	4, 4.3, 4.8, 5, 5.5, 6.5	3.8, 4.6 ,5.5 ,6.3
Height (mm)	2, 3, 4, 5, 6	2, 3, 4, 5, 6, 8	2, 3, 4, 5, 6, 7
Angle (°)	0	0	0
sterility	Non Sterile	Sterile	Non Sterile

Substantial equivalence discussion: As shown in the table above, TAV Medical titanium healing caps are Substantial equivalent in all features. A minor difference exists in the diameter dimensions however this difference is not significant since all subject device diameters are within the predicate devices dimensions range. One more difference exists in terms of sterility condition. This difference is covered by the reference device which is provided non-sterile similarly to TAV Medical titanium healing cap. Like in the predicate devices the

healing cap is screwed into the implant directly in trans-mucosal healing protocol. Cover screw is used in submucosal healing protocol.

Zirconia Healing Cap

Feature	TAV Medical	MIS	Noris Medical
Product Code	NHA	NHA	NHA
K#	K170131	K112162, K040807	K140440
Product Name	Zirconia Healing Cap	Titanium Healing Cap	Titanium Healing Cap
Product Description	Used to allow the gingiva to heal around the gingiva	Used to allow the gingiva to heal around the gingiva	Used to allow the gingiva to heal around the implant
Material	Zirconia	Titanium Alloy + Anodize	Titanium Alloy
Diameter (mm)	4, 4.7, 5.5	4, 4.3, 4.8, 5, 5.5, 6.5	3.8, 4.6 ,5.5 ,6.3
Height (mm)	2, 3, 4, 5, 6	2, 3, 4, 5, 6, 8	2, 3, 4, 5, 6, 7
Angle (°)	0	0	0
Sterility	Non Sterile	Sterile	Non Sterile

Substantial equivalence discussion: As shown in the table above, TAV Medical zirconia healing caps are Substantial equivalent since it is the same in most features. The only features that differ from the subject device are material and sterility conditions. In terms of materials TAV Medical healing cap is made of zirconia while titanium is utilized for the predicate devices healing caps. In order to assure that this difference does not compromise the subject device performance, thorough mechanical and biological tests were performed with satisfactory results.
In terms of sterility condition, this difference was covered by the reference device which is provided non-sterile similarly to TAV Medical zirconia healing cap.

PEEK Healing cap

Feature	TAV Medical	MIS
Product Code	NHA	NHA
K#	K170131	K112162, K040807
Product Name	TAV Healing Cap	Plastic healing cap
Product Description	Used to allow the gingiva to heal around the gingiva	Used to allow the gingiva to heal around the gingiva
Material	PEEK	PEEK
Height (mm)	4, 6, 8	4, 6, 8
Sterility	Non sterile	Non sterile

Substantial equivalence discussion: As shown in the table above, TAV Medical PEEK healing caps are substantial equivalent in all features.

Titanium Abutments, Straight

Feature	TAV Medical	MIS
Product Code	NHA	NHA
K#	K170131	K112162, K040807
Product Name	Titanium Abutments	Titanium Abutments
Product Description	An accessory to endosseous dental implants to support a prosthetic device	An accessory to endosseous dental implants to support a prosthetic device
Material	Titanium Alloy + Anodized	Titanium Alloy + Anodized
Diameter (mm)	3.8, 4.8, 5.2, 5.5	4.8, 5.5, 5.6, 5.8, 6.3
Height (mm)	0.5, 1, 2, 3	1, 2, 3
Length (mm)	7, 7.5, 9, 10, 11	7, 7.5, 8
Angle (°)	0	0
Sterility	Non Sterile	Non Sterile

Titanium Abutments, Angulated

Feature	TAV Medical	MIS
Product Code	NHA	NHA
K#	K170131	K112162, K040807
Product Name	Titanium Abutments	Titanium Abutments
Product Description	An accessory to endosseous dental implants to support a prosthetic device	An accessory to endosseous dental implants to support a prosthetic device
Material	Titanium Alloy + Anodize	Titanium Alloy + Anodize
Diameter (mm)	3.8, 4.8, 5.0, 5.5	4, 4.8, 4.9, 5.2, 5.5, 5.6, 5.8, 5.9 6
Height (mm)	0.5, 1, 2, 3	1, 2, 3
Length (mm)	6, 7, 8, 9	7, 7.3, 7.5, 8
Angle (°)	12, 15, 20, 25	10, 15, 20, 25
Sterility	Non Sterile	Non Sterile

Substantial equivalence discussion: As shown in the table above, TAV Medical Titanium abutments are substantial equivalent in all features. Minor difference in the angulated abutment lengths is not significant and covered by the mechanical tests performed by TAV Medical with satisfactory results.

PEEK Temporary Abutments, Straight

Feature	TAV Medical	SGS	A.B Dental Devices Ltd.
Product Code	NHA	NHA	NHA
K#	K170131	K 133362	K132125
Product Name	PEEK Temporary Abutments	Anatomic straight peek abutments	Temporary Anatomic Anti Rotation Abutment
Product Description	Temporary restoration up to 180 days	Temporary restoration up to 30 days	Temporary restoration
Material	PEEK CLASSIX	PEEK CLASSIX	PEEK CLASSIX
Diameter (mm)	5.5	5.5	4.7
Height (mm)	1, 2, 3	1,2,3mm	1,2,3mm
Length (mm)	8, 11	9 mm	7.5mm
Angle (°)	0	0	0
Sterility	Non Sterile	Non Sterile	Non Sterile

PEEK Temporary Abutments, Angulated

Feature	TAV Medical	A.B Dental Devices LTD
Product Code	NHA	NHA
K#	K170131	K132125
Product Name	PEEK Temporary Abutments	Temporary Anatomic Anti Rotation Abutment
Product Description	Temporary restoration up to 180 days	Temporary restoration
Material	PEEK CLASSIX	PEEK CLASSIX
Diameter (mm)	5.5	4.7
Height (mm)	1, 2, 3	1,2,3mm
Length (mm)	7, 6, 10	9 mm
Angle (°)	15, 25	15,25
Sterility	Non Sterile	Non Sterile

Substantial equivalence discussion: As shown in the table above, TAV Medical PEEK abutments are Substantial equivalent in most features. The difference in duration of use is that TAV Medical uses the INVIBIO PEEK-CLASSIX™ Polymer for dental applications of up to 180 days conforming to INVIBIO recommendations. TAV Medical has performed mechanical testing to evaluate the performance of its PEEK abutment to duration of 180 days with satisfactory results. Minor differences in the length are not significant and were covered by mechanical tests performed with satisfactory results.

Ball Attachment Abutment

Feature	TAV Medical	MIS
Product Code	NHA	NHA
K#	To be assigned	K112162, K040807
Product Name	Ball Attachment	Ball Attachment
Product Description	Removable (overdenture) restorations	Removable (overdenture) restorations
Material	Titanium Alloy + Anodize	Titanium Alloy + Anodize
Diameter (mm)	2.5	2.25
Height (mm)	1, 2, 3, 4, 5	1, 2, 3, 4, 5
Angle (°)	0	0
Sterility	Non Sterile	Non Sterile

The Ball attachment is also supplied as a kit containing a complementary metal housing, plastic caps and impression coping parts.

Substantial equivalence discussion: As shown in the table above, TAV Medical ball attachment abutments are substantial equivalent in all features.

Locker abutment

TAV Medical Zirconia locker abutment is supplied in two different configurations:

Locker type	Material
TAV Zirconia Locker full Zirconia body (Including a screw)	Zirconia (Screw is made of Titanium)
or,	
Zirconia body Locker with a titanium base. (Including a screw)	Zirconia & Titanium (Screw is made of Titanium)

TAV Zirconia locker full Zirconia body

Feature	TAV Medical	MIS
Product Code	NHA	NHA
K#	K170131	K112162, K040807
Product Name	Zirconia Locker	Locator
Product Description	Removable attachment system	Removable attachment system
Material	Zirconia	Titanium Nitride Coated Titanium
Height (mm)	0, 1, 2, 3, 4, 5, 6	0, 1, 2, 3, 4, 5, 6
Angle (°)	0	0
Sterility	Non Sterile	Non Sterile

TAV Zirconia Locker with Titanium base

Feature	TAV Medical	MIS
Product Code	NHA	NHA
K#	K170131	K112162, K040807
Product Name	Zirconia Locker	Locator
Product Description	Removable attachment system	Removable attachment system
Material	Zirconia , Titanium	Titanium Nitride Coated Ti
Height (mm)	2, 3, 4, 5, 6	0, 1, 2, 3, 4, 5, 6
Angle (°)	0	0
Sterility	Non Sterile	Non Sterile

The locker is also supplied as a kit containing a complementary metal housing, plastic caps and impression coping parts.

Substantial equivalence discussion: As shown in the table above, TAV Medical Locker abutments are substantial equivalent most features. The only feature that differs from the subject device is the material. In terms of materials TAV Medical Locker is made of zirconia while titanium is utilized for the predicate device. In order to assure that this difference does not compromise the subject device performance, thorough mechanical and biological tests were performed with satisfactory results.

Non clinical testing

Biocompatibility

TAV Medical Dental Implant System products were tested and evaluated for materials biocompatibility according to ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." Requirements and according to 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" in order to demonstrate the biocompatibility of the system.

Sterilization validation and shelf life

Sterilization validation tests were conducted in compliance with ANSI/AAMI/ISO 11137 parts 1 and 2. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Pyrogenicity of the sterile provided devices was tested using LAL method with satisfactory results that met the acceptance criteria as required by USP <85> and <161>.

Accelerated aging have been applied on the final packaging followed by a real time shelf life aging validation for 5 years shelf life.

Human Factors Study
Human factors study was performed in order to evaluate the safe handling of the sterile single unit packaging. The study's criteria were met and passed successfully. Positive feedbacks received from the users participated in the study.

Performance Testing
TAV Medical Dental Implant System 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 consensus standards were reviewed for determining required bench testing. Bench testing was performed to demonstrate that the TAV Medical Dental Implant System meets existing acceptance criteria similar to other predicate devices. The device does not require EMC and Electrical Safety evaluation.

Descriptive information, laboratory bench testing, and biocompatibility testing are provided to demonstrate Tav Medical Dental Implant System meets its design specifications, performs as intended. The system was evaluated through design verification testing including the following: Implant to abutment compatibility testing, Static and Dynamic fatigue testing, Corrosion testing, Surface finish analysis & Zirconia Material testing.

The non-clinical testing results showed that the proposed dental implant system meet the device requirements and is considered equivalent to its predicate device. The subject devices and the predicate device share the same intended use and technological characteristics.

Animal Testing
No Animal studies were performed.

Clinical testing
No clinical studies were performed.

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 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
4.	ISO 10993-11:2006	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
5.	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
6.	ISO 10993-18:2009	Biological evaluation of medical devices. Chemical characterization of materials
7.	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
8.	ISO 11137-2:2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
9.	AAMI TIR 33:2005	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method VDmax
10.	ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
11.	ISO 14801:2007	Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants
12.	ASTM F746-04	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials
13.	ASTM F1980-07(2011)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
14.	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
15.	ISO 15223-1: 2012	Symbols to be used with medical device labels, labelling, and information to be supplied: Part 1: General requirements
16.	ISO 13356:2008	Implants for surgery — Ceramic materials based on

#	Standard #	Standard Title
		yttria-stabilized tetragonal zirconia (Y-TZP)

Summary

Based on the substantial equivalence discussion, performance testing results, and compliance to applicable standards, TAV Medical Dental Implant System was proven to be substantially equivalent to its predicate device.