7/15/22

Suncoast Dental, Inc. dba Tatum Surgical
℅ Melissa Burbage
RA Sr Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K213576
Trade/Device Name: Tatum Surgical Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 9, 2021
Received: November 10, 2021

Dear Melissa Burbage:

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 Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213576

Device Name
Tatum Surgical Dental Implant System

Indications for Use *(Describe)*

The Tatum Surgical Integrity Tapered, "T" and "S" Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prothesis to restore chewing function. It may be used with single-stage or two- stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

The Tatum Surgical Dental "P" Plateau Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be used for single or multiple unit restorations and is indicated for delayed loading, placed with conventional two-stage surgical process with secondary and transmucosal healing.

The Tatum Surgical One-Piece Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be used for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The 3.0 mm diameter Tatum Surgical One-Piece Implant must be splinted if two or more are used adjacent to each other.

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

Tatum Surgical Dental Implant System

Tatum Surgical

July 15, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Suncoast Dental, Inc. dba Tatum Surgical 4500 140th Avenue North Suite 112 Clearwater, FL 33762 Telephone: +1 727-536-4880 Fax: +1 727-531-6005
Official Contact	Tony Fiorello, President; Freddie Dusold, Compliance Officer
Representative/Consultant	Melissa Burbage Kevin A. Thomas, PhD; Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com; flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Tatum Surgical Dental Implant System
Common Name	Dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Primary Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K133510, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA.

Additional Predicate Devices
K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K180282, MIS Internal Hex Dental Implant System, MIS Implants Technologies Ltd

K122231, Xpeed AnyRidge Internal Implant System, MegaGen Implant
K061410, Zimmer Dental (Advent) Implant System, Zimmer Dental, Inc.
K122231, Xpeed AnyRidge Internal Implant System, MegaGen Implant
K111581, NobelActive 3.0 Angled Abutment, Nobel Biocare USA, LLC
K092035, Bicon Implants with 2.5 mm Internal Connection, Bicon LLC
K171728, MOR Implant, Sterngold
K071235, K063523, K052997, Zimmer One-Piece Implant, Zimmer Dental
K093595, CeraRoot Implant System, Oral Iceberg S.L.
K110548, Juell OSI O-ball Abutment Dental Implant, Juell Dental

INDICATIONS FOR USE STATEMENT

The Tatum Surgical Integrity Tapered, "T" and "S" Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

The Tatum Surgical Dental "P" Plateau Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be for single or multiple unit restorations and is indicated for delayed loading, placed with conventional two-stage surgical process with secondary and transmucosal healing.

The Tatum Surgical One-Piece Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be used for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The 3.0 mm diameter Tatum Surgical One-Piece Implant must be splinted if two or more are used adjacent to each other.

SUBJECT DEVICE DESCRIPTION

The subject device includes three (3) two-piece implant systems that have connections and prosthetic components in multiple designs unique to each system, including straight and angled abutments intended for single-unit and multiple-unit restorations. The subject device also includes one (1) one-piece implant system, in which the abutment portion is integral with the implant portion.

Tatum Surgical Dental Implant System

Implant Line	Integrity Tapered Implant System	Unipost System		"P" Plateau Implant System	One-Piece Implant System
		"T" Tapered Implants	"S" Straight Implants		
Image *Not to Scale*					
Description	Tissue or Bone Level, threaded, tapered body, root-form implant.	Tissue Level, threaded root-form implant.		Bone Level, finned, tapered body, root-form implant.	One-piece implant/abutment, tapered body, threaded root-form implant.
		Tapered body	Straight body		
Diameters	3.7 – 8.0 mm	3.5 – 8.0 mm		4.5, 5.0 mm	3.0 – 6.0 mm
Lengths	9 – 20 mm (no 20 mm length for 7 and 8 mm Ø)	11 – 20 mm (no 20 mm length for 7 and 8 mm Ø)		6 – 11 mm	11 – 17 mm
Abutments	• Integrity Cover Screw • Integrity Healing Cap • Integrity Healing Cuff • Integrity Platform Switch Healing Cuff • Integrity Post 0°, 15° • Integrity Platform Switch 0°, 15°, 30 • Integrity One-Piece • Integrity Temporary Abutments • Integrity Ball Abutment	• Unipost Healing Screw • Unipost Healing Cuff • Unipost Abutments 5 mm height 0°, 10°, 20°, 30° • Unipost Abutment 9 mm height 0°, 10°, 20°, 30° • Unipost Temporary Abutment • Unipost "O" Ball Abutment		• Healing Abutment • Non-shouldered Abutment 0°, 15° • Shouldered Abutment • "O" Ball Abutment	• Straight Abutment • Angled Abutment 15° • Ball Abutment
Screws	• 2.0 RH Integrity 3.7-5.0 • 2.5 RH Integrity 6.0-8.0	• Healing Cuff Screw Uni • Unipost Abutment Screw		none	n/a

EQUIVALENCE TO MARKETED DEVICES

Two-Piece Implants – Standard

Indications for the standard two-piece implant systems are compared to those of the primary predicate K133510, and to the additional predicates K102034, K180282, K061410, and K122231. The IFUS for the subject device is substantially equivalent to that of the primary predicate K133510 and the additional predicate devices. Slight differences in the language of the IFUS do not affect the intended use as an endosseous dental implant and dental implant abutments for support of a prosthesis to restore chewing function.

The two-piece implant subject device offers two implant placement types: bone level and tissue level. The bone level placement subject device implants are similar to the primary predicate K133510, additional

predicates K102034, K180282, K122231, and K092035. The tissue level placement subject device implants are similar to the additional predicate K061410.

The two-piece implant subject device has an internal connection just as the other two-piece implants including the primary predicate K133510, and additional predicates K102034, K180282, and K061410, and K122231; the only difference is the type of internal connection. The two-piece implant subject device has implant diameters ranging from 3.5 mm to 8.0 mm (3.5, 3.7, 4.0, 4.5, 5.0, 6.0, 7.0, and 8.0 mm). The smallest diameter is similar to many of the predicates. The largest diameter is similar to the additional predicate K102034 which also has an 8 mm diameter, and similar to the additional predicate K122231 which has an 8.4 mm diameter. The two-piece subject device implants have implant lengths ranging from 9 mm to 20 mm (9, 11, 14, 17, and 20 mm); the two larger diameter implants (7 mm and 8 mm) are not offered in 20 mm length. The endosseous length of the subject device tissue level Integrity Tapered Implant is 1.5 mm less than the bone level length, resulting in lengths ranging from 7.5 mm to 18.5 mm (9, 11, 14, 17, and 20 mm). The smallest subject device endosseous length of 7.5 mm is similar to the primary predicate K133510, the additional predicate K102034, the additional predicate K180282, the additional predicate K061410 (implants with 8 mm length), and the additional predicate K122231 (implants with 7.7 mm length). The shortest subject device endosseous length is most similar to the additional predicate K122231 (implants with 7.7 mm length). The two-piece subject device "S" Implant System has a hole in the apical tip of the implant similar to additional predicate K061410.

The two-piece implant subject device has the same material, titanium alloy (Ti-6Al-4V) as the additional predicate K102034, additional predicate K092035, additional predicate K061410, and additional predicate K122231. The two-piece implant subject device has a blasted surface treatment same as the additional predicate device K102034. The two-piece subject device implants are provided sterile for single patient, single use, which is same as the primary predicate and additional predicate devices.

Two-Piece Implant Systems – "P" Plateau Implant System (Press-fit)

Indications for the "P" Plateau Implant System (press-fit) two-piece implant systems are compared to the primary predicate K133510 and to additional predicates K102034, K180282, and K092035. The IFUS for the subject device is substantially equivalent to that of the primary predicate K133510, except that the subject device is limited to delayed loading (two-stage procedure). Slight differences in the language of the IFUS do not affect the intended use as an endosseous dental implant and dental implant abutments for support of a prosthesis to restore chewing function.

The longest length of the subject device implants is similar to the additional predicate K180282. The two-piece subject device implant line that includes a "short" implant (defined as an implant less than 7 mm length) is the "P" Plateau Implant System, with lengths ranging from 6 mm to 11 mm (6, 8, and 11 mm). The shortest implant length is similar to the additional predicate K102034, the additional predicate K180282, and the additional predicate K092035.

The "P" Plateau Implant System (press-fit) two-piece implant subject device has the same material, titanium alloy (Ti-6Al-4V) as the additional predicate K102034, additional predicate K092035, additional predicate K061410, and additional predicate K122231. The two-piece implant subject device has a blasted surface treatment same as the additional predicate device K102034. The two-piece subject device implants are provided sterile for single patient, single use, which is same as the primary predicate and additional predicate devices.

Abutments

The subject device healing component offers diameters that correspond to the subject device implants, which range from 2.5 mm to 8.0 mm with a threaded or Morse connection. The range of diameters is similar the predicate devices. The subject device abutments are provided in diameters that correspond to the subject device implants, which range from 3.0 mm to 7.0 mm with a pentagon, threaded, or Morse taper connection, and angulation of 0°, 10°, 15°, 20°, and 30°. The diameters, connections, and angulations are similar the predicate device abutments. The subject device ball abutments are provided in diameters that correspond to the subject device implants, which range from 4.0 mm to 5.25 mm with a threaded or Morse taper connection. The subject device diameters are similar to those of the predicate device ball abutments. The subject device titanium housing and retention inserts with various retention levels are provided, similar to additional predicate device K180282 (OT-Equators & Ball Abutment system). All subject device abutments (healing components, abutments, and ball abutments) are made from titanium alloy (ASTM F136) which is same as the primary predicate and additional predicate devices.

One-Piece Implants

Indications for the subject device one-piece implants are compared to that of the additional predicates K171728, K052997, K063523, K071235, K093595, and K110548. The IFUS for the subject device is substantially equivalent to that of the additional predicate devices. Slight differences in the language of the IFUS do not affect the intended use as an endosseous dental implant and dental implant abutments for support of a prosthesis to restore chewing function.

The subject device one-piece implants have diameters ranging from 3.0 mm to 6.0 mm (3.0, 3.5, 4.0, 4.5, 5.0, and 6.0). The smallest subject device diameter is similar to that of the additional predicate devices; K171728, K052997, K063523, K071235, K093595, and K110548. The largest subject device diameter is similar to that of the additional predicate K093595. The subject device one-piece implants do not have diameters smaller or larger than any of the predicate devices. The subject device one-piece implants have lengths ranging from 11 mm to 17 mm (11, 14, and 17). The smallest subject device length is not less than that of many of the predicate devices. The longest subject device length is no longer than any of the predicates. The one-piece implant subject device is made from the same material, titanium alloy (Ti-6Al-4V) as is the additional predicate K052997, K063523, K071235 and additional predicate K110548. The subject device one-piece implants have a blasted surface treatment has a blasted surface treatment same as the additional predicate device K102034. The subject device one-piece implants have three abutment connections, straight, 15° angled, and ball. The abutment connections are similar to those of the additional predicate K171728 (straight and ball abutments), the additional predicate K052997, K063523, K071235 (straight and 17° angled abutments), the additional predicate K093595 (straight abutments), and the additional predicate K110548 (ball abutments). The one-piece implant subject device is provided sterile, for single patient, single use, which is same as the primary predicate and additional predicate devices.

PERFORMANCE DATA

Mechanical performance testing of the subject device was performed in conformance to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implant*s. This testing was performed to ensure that the strength of the subject device implants, in conjunction with the subject device abutments and abutment screws, is appropriate for the intended use. The worst-case implant and abutment configuration was determined for each implant system and was tested. The fatigue limit data

demonstrated that constructs of the subject device implants and abutments have sufficient strength for their intended use.

Surface area analysis was performed for the subject device implants with implant body lengths less than 7 mm and compared to a Bicon implant (cleared in K092035). Surface area analysis was performed for the subject device "P" Plateau Implant 4.5 x 6 mm implant compared to the Bicon Ø 4.0 x 5.0 mm implant (K092035; Bicon PN 340-255). Analyses of total surface area, surface area after 3 mm of bone loss, and bone-to-implant contact at placement were made using three-dimensional CAD models of the respective implants. For all conditions investigated, the surface area of the subject devices is greater than that of the Bicon predicate implant.

Modified surface testing was conducted on the subject device dental implants per FDA Guidance *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments,* issued May 12, 2002. The subject device dental implants have a surface that is grit blasted using aluminum oxide and then passivated. The information regarding the modified surface is provided in this submission, including the composition of the blast media and evidence for the removal of particles from the surface.

This sterilization cycle has been validated by the overkill method to a sterility assurance level (SAL) of 10^{-6} according to ISO 17665-1 *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*, and ISO/TR 17665-2 *Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1.* BET testing is conducted on every batch of final packaged, sterile product using the *Limulus* amebocyte lysate (LAL) test method according to ANSI/AAMI ST72 *Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing* and USP Chapter <85> regarding *Bacterial Endotoxins Test*.

The validated shelf life for the subject device components provided sterile is two (2) years. The shelf life was determined according to EN ISO 11607-1 *Packaging for terminally packaged medical devices to be sterilized – Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.* Package integrity of the sterile barrier was evaluated according to ASTM F2096 *Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) 2004*, and ASTM 1140-07 *Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.*

Cytotoxicity testing was performed according to ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-12 *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*.

CONCLUSION

The subject devices, the primary predicate device and reference devices have the same intended use and similar technological characteristics. They encompass a similar range of physical dimensions and are manufactured from the same materials. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Subject Device	
Tatum Surgical Dental Implant System Tatum Surgical	The Tatum Surgical Integrity Tapered, "T" and "S" Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Tatum Surgical Dental "P" Plateau Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be for single or multiple unit restorations and is indicated for delayed loading, placed with conventional two-stage surgical process with secondary and transmucosal healing. The Tatum Surgical One-Piece Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prosthesis to restore chewing function. It may be used for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The 3.0 mm diameter Tatum Surgical One-Piece Implant must be splinted if two or more are used adjacent to each other.
Primary Predicate Device	
K133510 Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários SA.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.
Additional Predicate Devices	
K102034 Blue Sky Bio Dental Implant System Blue Sky Bio, LLC	Intended Use for Two-Piece Implant Systems *For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis *For single tooth or multiple unit prosthesis *For single stage or two stage surgical procedure *For immediate placement and immediate function when multiple units are splinted and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. Multiple units may be splinted with a bar. In edentulous cases restored with a fixed prosthesis, four or more implants must be used. *Unsplinted narrow implants and angled abutments are not to be used in the posterior areas. *Taper Hex Implant System is compatible with Nobel Active implants and prosthetics *Double Hex Implant System is compatible with Astra double hex implants and prosthetics *Square Taper Implant System is compatible with Straumann Bone-Level implants and prosthetics
K180282 MIS Internal Hex Dental Implant System MIS Implants Technologies Ltd.	MIS dental implant systems 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 masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

K061410 Zimmer Dental (Advent) Implant System Zimmer Dental, Inc.	The Tapered Screw-Vent, Screw-Vent, AdVent, and Zimmer One-Piece 3.7 mm Dental Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.
K122231 Xpeed AnyRidge Internal Implant System MegaGen Implant	The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
K111581 NobelActive 3.0 Angled Abutment Nobel Biocare USA, LLC	The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.
K092035 Bicon Implants with 2.5 mm Internal Connection Bicon LLC	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.
K171728 MOR 3.0mm and PUR NP 3.2mm Implant Systems, MOR 2.1 x 18mm and 2.4x18mm Sterngold Dental, LLC	The MOR™ implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The MOR™ implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary.
K071235 (3.0 angled) K063523 (3.7 and 4.7 straight and angled) K052997 (3.0 and 3.7 straight) Zimmer One-Piece Zimmer Dental, Inc.	Zimmer One-Piece 3.0mmD Implants are indicated for the support and retention of fixed single-tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The 3.0mmD Zimmer One-Piece Implant must be splinted if two or more are used adjacent to each other, and may be immediately restored with a temporary prosthesis that is not in functional occlusion. Zimmer One-Piece 3.7mmD and 4.7mmD Implants are designed for use in the maxilla or mandible for immediate loading, or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.
K093595 CeraRoot Implant System Oral Iceberg S.L.	CeraRoot dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot implants can be placed in immediate or delayed tooth extractions. CeraRoot implants are not intended for immediate loading. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.
K110548 Juell OSI O-ball Abutment Dental Implant Juell Dental	The OSI O-ball Abutment implant is a self-tapping titanium threaded screw indicated for long term intra-bony fixation of upper and lower dentures in edentulous cases. These devices will permit immediate splinting and ability and short-term fixation of failing crown and bridge installations, for full or partial edentulism. They can be used in the anterior regions of the maxillary and mandibular arches and are indicated for immediate loading when there is good primary stability and appropriate occlusal load.

Feature	Subject Device		Primary Predicate	Additional Predicate		Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate
	Tatum Surgical Dental Implant System **Tatum Surgical**		K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K102034 Blue Sky Bio Dental Implant System Blue Sky Bio, LLC		K180282 MIS Internal Hex Dental Implant System MIS Implants Technologies Ltd.	K061410 (Advent) Zimmer Dental Implant System Zimmer Dental	K122231 Xpeed AnyRidge Internal Implant System MegaGen Implant	K111581 NobelActive 3.0 Angled Abutment Nobel Biocare USA, LLC	K092035 Bicon Implants with 2.5 mm Internal Connection Bicon LLC
Product Code	DZE, NHA		DZE, NHA	DZE, NHA		DZE, NHA	DZE	DZE, NHA	NHA	DZE
Reason for Predicate/ Reference Device	n/a		Implant narrow diameter 30° angled abutments	Implant wide diameter Short implant (6 mm) 30° Angled Abutments		Implant length (20 mm) Short implant (6 mm)	Tissue Level and hole in apical tip	Widest x longest (6x17) 10.0 abutment	3.0 Abutment	Surface area comparison
Integrity Tapered Implant										
Implant Placement	Bone Level	Tissue level	Bone level	Bone level	Bone level	Bone level	Tissue Level	Bone Level		
Prosthetic Interface Connection	Internal pentagon		Internal hex	Internal hex w/taper	internal square w/taper	Internal hex	Internal hex	Internal Hex		
Body/Platform Diameter, mm	3.7, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0		Titamax Smart – 3.3, 3.75, 4.0, 4.5, 5.0 Titamax Smart EX - 3.75, 4.0	Square taper – 3.3, 4.1, 4.8, 5.6, 7, 8	Double hex – 3.25, 3.5, 4.0, 5.0	Ø 3.3 – 10 ,11.5, 13, 16 Ø 3.75 – 8, 10, 11.5, 13, 16, 18, 20 Ø 4.2 – 6, 8, 10, 11.5, 13, 16, 18, 20 Ø 5.0 – 6, 8, 10, 11.5, 13, 16 Ø 6.0 – 6, 8, 10, 11.5, 13	3.7/4.5, 4.7/4.5, 4.7/5.7	Normal ridge – 4.0, 4.4, 4.9, 5.4, 5.9 low ridge – 6.4, 6.9, 7.4, 7.9, 8.4		
Total Lengths, mm	9, 11, 14, 17, 20 (no 20 mm length for 7 and 8 mm Ø)		Titamax Smart - 9, 11, 13, 15, 17 Titamax Smart EX - 9, 11, 13, 15, 17, 19	Square taper – 8, 10, 12, 14, 16	Double hex – 9, 11, 13, 15, 17		11, 13, 16, 19	Normal ridge – 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Low ridge – 7.9, 9.4, 10.9, 12.4, 14.4		
Endosseous Length, mm	Same as total length	7.5, 9.5, 12.5, 15.5, 18.5 (no 15.5 and 18.5 mm length for 7 and 8 mm Ø)	Same as total length	Same as total length	Same as total length	Same as total length	8, 10, 13, 16	Same as total length		
Implant Material	Titanium alloy (Ti6Al-4V)		CP Titanium, Gr.4	Titanium alloy (Ti6Al-4V)		Titanium TI-6Al-4V ELI	Titanium TI-6Al-4V ELI	CP Titanium, Gr 4 and Titanium TI-6Al-4V ELI		
Implant Endosseous Surface	Aluminum oxide blasted and passivated		Grit blasted and acid etched	Blasted with resorbable medium, or etched		Sand blasted and acid etched	MTX Blasted	Sand-blasted, Large grit, Acid-etched (SLA)		
Healing Components Cover screws, Healing caps, Healing cuffs	Coronal Ø: 3.25-8.0 mm Gingival Height: 0-5 mm Connection: Threaded Titanium Alloy (ASTM F136)		Healing Components Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136)	Healing Components Coronal Ø: Narrow, Reg, Wide Connection: Hex Titanium Alloy (ASTM F136)		Healing Components Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136)		Not stated in summary		
Abutments Post Abutment, Platform Switch, One-Piece Abutment, Temporary Abutment	Coronal Ø: 3.25-5.0 mm Gingival Height: 1.4-1.5 mm Angulation: 0°, 15°, 30° Connection: Pentagon or threaded Titanium Alloy (ASTM F136)		Abutments Coronal Ø: 3.3-5.0 Angulation: 0°, 17°, 30° Connection: Internal hex Titanium Alloy (ASTM F136)	Taper Hex Abutments Coronal Ø: Narrow, Reg, Wide Angulation: 0°, 15°, 25°, 30° Connection: Hex Titanium Alloy (ASTM F136)		Abutments Coronal Ø: Not stated in summary Angulation: 0°, 10°, 15°, 20°, 25° Connection: Hex Titanium Alloy ELI (ASTM F136)		Coronal Ø: 4.0-10.0 mm Length: 8.4-16.4 mm Angulation: 0°, 15°, 25° Connection: Internal pentagon or threaded Titanium Alloy (ASTM F136)	Coronal Ø: 3.0 mm Gingival Height: Not stated Angulation: 0°, 15° Connection: Internal Hex Titanium Vanadium Alloy	
Ball Abutment	Coronal Ø: 4.0-5.25 mm Gingival Height: 1-5 mm Connection: Threaded Titanium Alloy (ASTM F136) Nylon and Silicone Inserts		Ball-type abutments Coronal Ø: 3.3-5.0 Connection: Hex Titanium Alloy (ASTM F136)	Overdenture Abutment Coronal Ø: Narrow, Reg, Wide Connection: Threaded Titanium Alloy (ASTM F136)		Ball-type abutments Coronal Ø: Not stated in summary Connection: Internal Hex Titanium Alloy (ASTM F136) Nylon Inserts		Not stated in summary		

Feature	Subject Device	Primary Predicate	Additional Predicate		Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate
	Tatum Surgical Dental Implant System **Tatum Surgical**	K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K102034 Blue Sky Bio Dental Implant System Blue Sky Bio, LLC		K180282 MIS Internal Hex Dental Implant System MIS Implants Technologies Ltd.	K061410 (Advent) Zimmer Dental Implant System Zimmer Dental	K122231 Xpeed AnyRidge Internal Implant System MegaGen Implant	K111581 NobelActive 3.0 Angled Abutment Nobel Biocare USA, LLC	K092035 Bicon Implants with 2.5 mm Internal Connection Bicon LLC
Unipost T & S Implants									
Implant Placement	Tissue level	Bone level	Bone level	Bone level	Bone level	Tissue Level	Bone Level		
Prosthetic Interface Connection	Internal pentagon	Internal hex	Internal hex w/taper	internal square w/taper	Internal hex	Internal hex	Internal Hex		
Body/Platform Diameter, mm	3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0	Titamax Smart – 3.3, 3.75, 4.0, 4.5, 5.0 Titamax Smart EX - 3.75, 4.0	Square taper – 3.3, 4.1, 4.8, 5.6, 7, 8	Double hex – 3.25, 3.5, 4.0, 5.0	Ø 3.3 – 10 ,11.5, 13, 16 Ø 3.75 – 8, 10, 11.5, 13, 16, 18, 20 Ø 4.2 – 6, 8, 10, 11.5, 13, 16, 18, 20 Ø 5.0 – 6, 8, 10, 11.5, 13, 16 Ø 6.0 – 6, 8, 10, 11.5, 13	3.7/4.5, 4.7/4.5, 4.7/5.7	Normal ridge – 4.0, 4.4, 4.9, 5.4, 5.9 low ridge – 6.4, 6.9, 7.4, 7.9, 8.4		
Total Lengths, mm	11, 14, 17, 20 (no 20 mm length for 7 and 8 mm Ø)	Titamax Smart - 9, 11, 13, 15, 17 Titamax Smart EX - 9, 11, 13, 15, 17, 19	Square taper – 8, 10, 12, 14, 16	Double hex – 9, 11, 13, 15, 17		11, 13, 16, 19	Normal ridge – 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Low ridge – 7.9, 9.4, 10.9, 12.4, 14.4		
Endosseous Length, mm	7.5, 9.5, 12.5, 15.5, 18.5 (no 15.5 and 18.5 mm length for 7 and 8 mm Ø)	Same as total length	Same as total length	Same as total length	Same as total length	8, 10, 13, 16	Same as total length		
Apical Hole	No and Yes	No	No	No	No	Yes	No		
Implant Material	Titanium alloy (Ti6Al-4V)	CP Titanium, Gr.4	Titanium alloy (Ti6Al-4V)		Titanium TI-6Al-4V ELI	Titanium TI-6Al-4V ELI	CP Titanium, Gr 4 and Titanium TI-6Al-4V ELI		
Implant Endosseous Surface	Aluminum oxide blasted and passivated	grit blasted and acid etched	Blasted with resorbable medium, or etched		Sand blasted and acid etched	MTX Blasted	Sand-blasted, Large grit, Acid-etched (SLA)		
Healing Components Healing screws, Healing cuffs	Coronal Ø: 2.5-8.0 mm Gingival Height: 2.4-3.63 mm Connection: Threaded Titanium Alloy (ASTM F136)	Cover Screws and Healing Abutments Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136)	Cover Screws and Healing Abutments Coronal Ø: Narrow, Reg, Wide Connection: Hex Titanium Alloy (ASTM F136)		Cover Screws and Healing Abutments Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136)		Not stated in summary		
Abutments Unipost Abutment, Temporary Abutment	Coronal Ø: 3.0-7.0 mm Gingival Height: 0-5 mm Angulation: 0°, 20°, 30° Connection: Threaded Titanium Alloy (ASTM F136)	Abutments Coronal Ø: 3.3-5.0 Angulation: 0°, 17°, 30° Connection: Hex Titanium Alloy (ASTM F136)	Taper Hex Abutments Coronal Ø: Narrow, Reg, Wide Angulation: 0°, 15°, 25°, 30° Connection: Hex Titanium Alloy (ASTM F136)		Abutments Coronal Ø: Not stated in summary Angulation: 0°, 10°, 15°, 20°, 25° Connection: Hex Titanium Alloy ELI (ASTM F136)		Coronal Ø: 4.0-10.0 mm Length: 8.4-16.4 mm Angulation: 0°, 15°, 25° Connection: Internal pentagon or threaded Titanium Alloy (ASTM F136)	Coronal Ø: 3.0 mm Gingival Height: Not stated Angulation: 0°, 15° Connection: Internal Hex Titanium Vanadium Alloy	
Ball Abutment	Coronal Ø: 3.5-4.5 mm Gingival Height: 1-5 mm Connection: Threaded Titanium Alloy (ASTM F136) Nylon and Silicone Inserts	Ball-type abutments Coronal Ø: 3.3-5.0 Connection: Hex Titanium Alloy (ASTM F136)	Overdenture Abutment Coronal Ø: Narrow, Reg, Wide Connection: Threaded Titanium Alloy (ASTM F136)		Ball-type abutments Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136) Nylon Inserts		Not stated in summary		
P Implants									
Implant Placement	Bone level		Bone level		Bone level				Bone level
Prosthetic Interface Connection	Morse taper		Internal hex w/ taper		Internal hex				Morse taper
Body/Platform Diameter, mm	4.5, 5.0		4.8, 5.6, 7.0, 8.0		Ø 4.2 – 6, 8, 10, 11.5, 13, 16, 18, 20 Ø 5.0 – 6, 8, 10, 11.5, 13, 16 Ø 6.0 – 6, 8, 10, 11.5, 13				Ø 4.0 – 5, 8, 11 Ø 4.5 – 8, 11 *From marketing material, not stated in 510(k) Summary*
Total Lengths, mm	6, 8, 11		6						
Endosseous Length, mm	Same as total length		7.8		Same as total length				Same as total length
Implant Collar, mm	None		1.8		None				None

Feature	Subject Device	Primary Predicate	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate
	Tatum Surgical Dental Implant System **Tatum Surgical**	K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K102034 Blue Sky Bio Dental Implant System Blue Sky Bio, LLC	K180282 MIS Internal Hex Dental Implant System MIS Implants Technologies Ltd.	K061410 (Advent) Zimmer Dental Implant System Zimmer Dental	K122231 Xpeed AnyRidge Internal Implant System MegaGen Implant	K111581 NobelActive 3.0 Angled Abutment Nobel Biocare USA, LLC	K092035 Bicon Implants with 2.5 mm Internal Connection Bicon LLC
Implant Material	Titanium alloy (Ti6Al-4V)		Titanium alloy (Ti6Al-4V)	Titanium TI-6Al-4V ELI				Titanium alloy (Ti6Al-4V)
Implant Endosseous Surface	Aluminum oxide blasted and passivated		Blasted with resorbable medium, or etched	Sand blasted and acid etched				Grit blasted, acid etched, and hydroxylapatite
Healing Components Healing Abutments	Coronal Ø: 4.5-5.0 mm Connection: Morse Titanium Alloy (ASTM F136)		Cover Screws and Healing Abutments Coronal Ø: Narrow, Reg, Wide Connection: Hex Titanium Alloy (ASTM F136)	Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136)				
Abutment Non-shouldered Abutment, Shouldered Abutment	Coronal Ø: 4.5-5.0 mm Gingival Height: 2-6 mm Angulation: 0°, 15° Connection: Morse Titanium Alloy (ASTM F136)		Taper Hex Abutments Coronal Ø: Narrow, Reg, Wide Angulation: 0°, 15°, 25°, 30° Connection: Hex Titanium Alloy (ASTM F136)	Coronal Ø: Not stated in summary Angulation: 0°, 10°, 15°, 20°, 25° Connection: Hex Titanium Alloy ELI (ASTM F136)				
Ball Abutment	Coronal Ø: 4.5-5.0 mm Gingival Height: 1.5-3.5 mm Connection: Morse Titanium Alloy (ASTM F136) Nylon and Silicone Inserts		Overdenture Abutment Coronal Ø: Narrow, Reg, Wide Connection: Threaded Titanium Alloy (ASTM F136)	Coronal Ø: Not stated in summary Connection: Hex Titanium Alloy (ASTM F136) Nylon Inserts				
How Provided								
Sterility	Sterile implants, nonsterile abutments	Sterile implants, nonsterile abutments	Sterile implants, nonsterile abutments	Sterile implants, nonsterile abutments	Sterile implants	Sterile implants, nonsterile abutments	Nonsterile abutments	Sterile implants, nonsterile abutments
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

Table of Substantial Equivalence – Technological Characteristics – One-Piece Implants

Feature	Subject Device	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate
	Tatum Surgical	K171728 MOR 3.0mm and PUR NP 3.2mm Implant Systems, MOR 2.1 x 18mm and 2.4x18mm Sterngold Dental, LLC	K071235 (3.0 angled), K063523 (3.7 & 4.7 straight & angled) K052997 (3.0 and 3.7 straight) Zimmer One-Piece Zimmer Dental, Inc.	K093595 CeraRoot Implant System Oral Iceberg S.L.	K110548 OSI O-ball Abutment Dental Implant Juell Dental
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Reason for Predicate/ Reference Device	n/a	Straight & Ball Abutment Narrow x short (2.1x10) Narrow x long (2.1&18)	Straight & Angled Abutment Narrow x short (3.0x10)	Straight Abutment Wide x short (6.5x8) Wide x long (6.5x14)	Ball Abutment Wide x long (4.5x18)
One-Piece Implants, Straight Abutment					
Body/Platform Diameter, mm	3.0, 3.5, 4.0, 4.5, 5.0, 6.0	2.1, 2.4, 3.0	3.0, 3.7, 4.7	3.5, 4.1, 4.8, 6.0, 6.5	
Endosseous Lengths, mm	11, 14, 17 (no 11 for angled)	10, 13, 15, 18	10, 11.5, 13, 16 (no 16 for 3.0)	8, 10, 12, 14	
Abutment Collar, mm	1.5	Not stated in 510(k) summary	0.5	3.5	
Abutment Type	Straight	Straight	Straight	Straight	
Implant Material	Titanium alloy (Ti6Al-4V)	Wrought titanium 6AL-4V ELI	Titanium alloy (Ti6Al-4V)	Zirconia	
Implant Endosseous Surface	Aluminum Oxide (Al_2O_3) Blasted, passivated	Roughened - blasted and acid Etched	Grit blasted	None	
Abutment	Straight	Straight	Straight	Straight	
One-Piece Implants, Angled Abutment					
Body/Platform Diameter, mm	3.0, 3.5, 4.0, 4.5		3.0, 3.7, 4.7		
Endosseous Length, mm	14, 17		10, 11.5, 13, 16 (no 16 for 3.0)		
Abutment Collar, mm	1.5		0.5		
Implant Material	Titanium alloy (Ti6Al-4V)		Titanium alloy (Ti6Al-4V)		
Implant Endosseous Surface	Aluminum Oxide (Al_2O_3) Blasted, passivated		Grit blasted		
Abutment	15°		17°		

Feature	Subject Device	Additional Predicate	Additional Predicate	Additional Predicate	Additional Predicate
	Tatum Surgical	K171728 MOR 3.0mm and PUR NP 3.2mm Implant Systems, MOR 2.1 x 18mm and 2.4x18mm Sterngold Dental, LLC	K071235 (3.0 angled), K063523 (3.7 & 4.7 straight & angled) K052997 (3.0 and 3.7 straight) Zimmer One-Piece Zimmer Dental, Inc.	K093595 CeraRoot Implant System Oral Iceberg S.L.	K110548 OSI O-ball Abutment Dental Implant Juell Dental
One-Piece Implants with Ball Abutment					
Body/Platform Diameter, mm	3.0, 3.5, 4.0, 4.5, 5.0	2.1, 2.4, 3.0			3.0, 3.5, 4.0, 4.5
Endosseous Lengths, mm	11, 14, 17	10, 13, 15, 18			10, 13, 15, 17, 18
Abutment Collar, mm	1.5	Not stated in 510(k) summary			Not stated in 510(k) summary
Implant Material	Titanium alloy (Ti6Al-4V)	Wrought titanium 6AL-4V ELI			Titanium alloy (Ti6Al-4V) F136
Implant Endosseous Surface	Aluminum Oxide (Al_2O_3) Blasted, passivated	Roughened - blasted and acid etched			Blasted and clean
Abutment	Ball	Ball			Ball
How Provided					
Sterility	Sterile	Sterile	Sterile	Sterile	Sterile
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use