August 27, 2020

Sanlilar Tibbi Cihazlar Medikal Kimya Sanayi Ticaret Ltd. Sti
% Semih Oktay
President
CardioMed Device Consultants
3168 Braverton St., Suite 200
Edgewater, Maryland 21037

Re: K192062
Trade/Device Name: Nucleoss T6 Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 24, 2020
Received: July 27, 2020

Dear Semih Oktay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K192062

Device Name: Nucleoss T6 Dental Implant System

Indications for Use:

Nucleoss T6 Dental Implants are intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function. Nucleoss T6 Dental Implants are intended for delayed loading after 12 weeks.

Nucleoss Abutments and Prosthetic parts are intended for use with Nucleoss T6 Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures for edentulous or partially edentulous patients.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
[as required by 21 CFR 807.92(c)]

Nucleoss T6 Dental Implant
510(k) K192062

DATE PREPARED	August 27, 2020
APPLICANT INFORMATION	Ezgi Ozbudak 10018 Sok. No: 7 ITOB Organize Sanayi Bölgesi Tekeli Menderes/IZMIR TURKEY Phone: +90 232 799 03 04 Email: kalite@nucleoss.com
CONTACT INFORMATION	Semih Oktay, Ph.D, President and CEO, CardioMed Device Consultants Phone:(410) 674-2060 Email: soktay@cardiomedllc.com
TRADE NAME	Nucleoss T6 Dental Implant System
DEVICE CLASSIFICATION	Class II per 21 CFR §872.3640
CLASSIFICATION NAME	Endosseous dental implant
PRODUCT CODE	DZE NHA
PREDICATE DEVICE	TPure Dental Implant (K160850)
REFERENCE DEVICES	Straumann Dental Implant System (K171784) Thommen Medical (K093615)

INDICATIONS FOR USE

Nucleoss T6 Dental Implants are intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function. Nucleoss T6 Dental Implants are intended for delayed loading after 12 weeks.

Nucleoss Abutments and Prosthetic parts are intended for use with Nucleoss T6 Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures for edentulous or partially edentulous patients.

DEVICE DESCRIPTION

The Nucleoss T6 Dental Implant is a bone level implant constructed of unalloyed titanium (ISO 5832-2). The surface of the T6 implant is a sand-blast and acid-etch (SLA) surface treatment.

T6 Implants

Nucleoss T6 implants have a cylindrical form design, with a double lead thread form and two helical anti-rotation grooves. The thread structure is a reverse buttress. The internal structure is designed as a conical internal hex connection with 140 degrees.

The Nucleoss Dental Abutments are intended for use with the Nucleoss T6 Dental Implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.

Abutments

The Nucleoss Dental Abutments consist of the following designs: Standard Straight, Esthetic Straight, Esthetic Angled, Angled, Ball and Equator, Cover, Gingiva Former and Screw. Nucleoss Dental Abutments are cement-retained and screw-retained restorations and intended for placement on Nucleoss T6 implants with diameters of 3.5, 4.1 and 4.8 mm. The connection to the dental implant is achieved by an internal hexagon.

These devices are constructed of titanium alloy (Ti6Al4V ELI) per ISO 5832-3.

The Standard Straight Abutment is intended for cement-retained single and multiple restorations. There is no angulation. The Standard Straight abutments can be used in anterior and posterior maxillary and/or mandibular arches. Prior to cementing in place, the Standard Straight abutment is secured on the implant with a screw.

The Esthetic Straight Abutment is intended for cement-retained single and multiple restorations. There is no angulation. The Esthetic Straight abutments can be used in anterior and posterior maxillary and/or mandibular arches. Prior to cementing in place, the Esthetic Straight abutment is secured on the implant with a screw. The front and back gingival heights of these abutments are different from each other. The front heights are shorter and the back heights are greater. These height differences offer the dentist an esthetically beneficial option as required.

The Esthetic Angled Abutment is intended for cement-retained single and multiple restorations. The Esthetic Angled Abutment is provided in angles of 15 and 25 degrees for cases where angle correction is required. The Esthetic Angled abutments can be used in anterior and posterior maxillary and/or mandibular arches. Prior to cementing in place, the Esthetic Angled abutment is secured on the implant with a screw. The front and back gingival heights of these abutments are different from each other. The front heights are shorter and the back heights are greater. These height differences offer the dentist an esthetically beneficial option as required.

The Angled Abutment is intended for cement-retained single and multiple restorations. The Angled Abutment is provided in angles of 15 and 25 degrees for cases where an angle correction is required. The Angled Abutment can be used in anterior and posterior maxillary and/or

mandibular arches. Prior to cementing in place, the Angled Abutment is secured on the implant with a screw.

The Ball abutment is intended for overdenture restorations. The top part of the abutment is designed as a ball with a dimeter of 2.25 mm. There is no angulation. The Ball Abutment can be used in anterior and posterior maxillary and/or mandibular arches. The Ball abutment is inserted and combined with the fixture in order to support the overdenture.

The Equator abutment is intended for overdenture restorations. There is no angulation. The Equator Abutment can be used in anterior and posterior maxillary and/or mandibular arches. The Equator abutment is inserted and combined with the fixture in order to support the overdenture.

The Abutments are single-use devices. The Abutments are provided non-sterile for end-user steam sterilization.

Covers and Gingiva Formers

The Nucleoss Cover and Gingiva Former are used during the healing and prosthesis period following surgical placement of the dental implant. All of these devices are constructed of titanium alloy (Ti6Al4V ELI) per ISO 5832-3.

Covers and Gingiva Formers are single-use devices. The Cover is provided sterile in the same packaging tube as the Nucleoss T6 Dental Implant. The Gingiva Formers are provided non-sterile for end-user steam sterilization.

Screws

The Nucleoss Dental Implant and Abutments devices also include screws for securing abutments to the implant to provide a secure coupling for the denture prosthetic attachment to the abutment. They are provided non-sterile and are packaged together with the abutments.

COMPARISON WITH PREDICATE DEVICES

A comparison of the Subject Device and its primary predicate has been conducted. The indications for use of the T6 is identical to that of the predicate device.

A comparison of the T6 and predicate device shows that the technological characteristics such as the components, design, materials, sterilization method, and operating principle of the T6 are similar to the currently marketed Tpure predicate device.

Comparison of Indications for Use Statements to Predicate and Reference Devices

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
	Nucleoss T6 Dental Implant System	**Nucleoss Tpure Implant System (K160850)**	**Straumann Dental Implant System (K171784)**	**Thommen Medical SPI Dental Implant, ELEMENT (K093615)**
Indications for Use Statement	Nucleoss T6 Dental Implants are intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function. Nucleoss T6 Dental Implants are intended for delayed loading after 12 weeks.	Nucleoss Tpure Implant system are medical devices intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function. Nucleoss Tpure Dental Implants are intended for delayed loading after 12 weeks.	Indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	SPI® Dental Implant, ELEMENT is for one-stage or two-stage surgical procedures. SPI Dental Implant, ELEMENT is intended for immediate placement and function on singletooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used in immediately loaded cases.

Comparison of Technological Characteristics to Predicate and Reference Devices

Technological Characteristics	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
	Nucleoss T6 Dental Implant System	**Nucleoss Tpure Implant System (K160850)**	**Straumann Dental Implant System (K1171784)**	**Thommen Medical SPI Dental Implant, ELEMENT (K093615)**
Material	Grade 4 commercially pure titanium conforming with ISO 5832-2	Grade 4 commercially pure titanium conforming with ISO 5832-2	Ti-13Zr alloy (trade named Roxolid) or Ti Grade 4	CP Titanium (ISO 5832-2)
Surface	Sand blasted Large grit Acid etched (SLA)	Sand blasted Large grit Acid etched (SLA)	Sand blasted Large grit Acid etched (SLActive)	Sand blasted, thermal acid etched
Implant Design	Two component / Bone level/ Cylindrical form	Two component / Bone level/Conical form	Bone level / Tissue level Internal connection	Bone level Internal connection / Root form
Implant body diameter (mm)	3.5, 4.1, 4.8	3.4, 3.8, 4.2, 5.0	3.3, 4.1, 4.8	3.5, 4.0, 4.5, 5.0, 6.0
Implant length (mm)	6.5, 8, 10, 12, 14, 17	8, 10, 12, 14	8, 10, 12, 14, 16, 18	6.5, 8, 9.5, 11, 12.5
Diameter x Length (mm)	3.5x8, 3.5x10, 3.5x12, 3.5x14, 3.5x17, 4.1x6.5, 4.1x8, 4.1x10, 4.1x12, 4.1x14, 4.1x17, 4.8x6.5, 4.8x8, 4.8x10, 4.8x12, 4.8x14, 4.8x17	3.4x10, 3.4x12, 3.4x14, 3.8x8, 3.8x10, 3.8x12, 3.8x14, 4.2x8, 4.2x10, 4.2x12, 4.2x14, 5.0x8, 5.0x10, 5.0x12, 5.0x14	3.3x8, 3.3x10, 3.3x12, 3.3x14, 3.3x16, 3.3x18 4.1x6, 4.1x8, 4.1x10, 4.1x12, 4.1x14, 4.1x16, 4.1x18 4.8x6, 4.8x8, 4.8x10, 4.8x12, 4.8x14, 4.8x16, 4.8x18	3.5x8, 3.5x9.5, 3.5x11, 3.5x12.5, 4.0x6.5, 4.0x8.0, 4.0x9.5, 4.0x11, 4.0x12.5 4.5x6.5, 4.5x8.0, 4.5x9.5, 4.5x11, 4.5x12.5, 5.0x6.5, 5.0x8.0, 5.0x9.5, 5.0x11, 5.0x12.5 6.0x6.5, 6.0x8.0, 6.0x9.5, 6.0x11, 6.0x12.5
Restoration	For single or multiple restorations	For single or multiple restorations	For single or multiple restorations	For single or multiple restorations
Implant connection	Internal	Internal	Internal	Internal
Surgical technique	Two stage surgical technique	Two stage surgical technique	One-stage or two-stage surgical technique	One-stage or two-stage surgical technique
Sterilization	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)

Comparison of Technological Characteristics of Abutments

Tecnological Characteristics	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Nucleoss T6 Dental Implant System	**Nucleoss Tpure Implant System (K160850)**
Device	Nucleoss T6 Standard Straight, Esthetic Straight, Esthetic Angled, Angled, Ball and Equator abutments, Gingiva Former and Cover	Nucleoss Tpure Straight, Angled, Ball, and Equator abutments, Gingiva Former and Cover
Material	Titanium alloy (Ti6Al4V ELI) per ISO 5832-3	Titanium alloy (Ti6Al4V ELI) per ISO 5832-3
Abutment Diameter (mm)	Standard Straight, Esthetic Straight, Esthetic Angled, Angled abutment: 4.3, 5.0, 6.0 mm Ball and Equator Abutment: 4.5 mm Gingiva Former: 4.3, 5.0, 6.0 Cover: 4.3, 5.0, 6.0	Straight and Angled abutment: 4.2, 5.0, 6.0 mm Ball and Equator Abutment Abutment: 4.5 mm Gingiva Former: 4.2, 5.0, 6.0 Cover: 4.2, 5.0, 6.0
Gingival Height (mm)	Standard straight abutment: 1.0, 1.5, 2.0, 3.0, 4.0, 4.5, 5.0 mm Esthetic straight abutment: 1.0-2.0, 2.0-3.0, 1.5-2.5, 2.5-3.5 mm Angled abutment: 1.0, 1.5, 2.0, 3.0, 4.0, 5.0 mm Esthetic angled abutment: 1.0-2.0, 2.0-3.0, 3.0-4.0 mm Ball and equator abutment: 1.5, 3.0, 5.0 mm Gingiva Former: 2.0, 4.0, 6.0 Cover: 0	Straight abutment: 1.0, 2.0, 3.0, 5.0 mm Angled abutment: 1.0, 2.0, 3.0, 4.0 mm Ball and equator abutment: 1.5, 3.0, 5.0 mm Gingiva Former: 2.0, 4.0, 6.0 Cover: 0

Comparison of Technological Characteristics of Abutments

Technological Characteristics	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Nucleoss T6 Dental Implant System	**Nucleoss Tpure Implant System (K160850)**
Abutment Design	Straight or Angled	Straight or Angled
Angulation	Standard straight abutment: 0º Esthetic straight abutment: 0º Angled abutment: 15º and 25º Esthetic angled abutment: 15º and 25º Ball and equator abutment: 0º Gingiva Former: 0º Cover: 0º	Straight abutment: 0º Angled abutment: 10°-20°-30° Ball and equator abutment: 0º Gingiva Former: 0º Cover: 0º
Restoration	The Standard straight abutment, Esthetic straight abutment, Angled abutment, Esthetic angled abutment are for single or multi unit restorations. The Ball and Equator abutments are only for multi unit restorations. There is no restoration type for cover and gingiva formers.	The Straight abutment, Angled abutment are for single or multi unit restorations. The Ball and Equator abutments are only for multi unit restorations. There is no restoration type for cover and gingiva formers.
Implant-Abutment connection	Internal	Internal
Sterilization	Nucleoss T6 Standard Straight, Esthetic Straight, Esthetic Angled, Angled, Ball Equator abutments and gingiva formers are provided non-sterile. Cover is packaged with the dental implant and sterilized via gamma irradiation.	The Nucleoss Tpure Straight abutment, Angled abutments, and gingiva formers are provided non-sterile. Cover is packaged with the dental implant and sterilized via gamma irradiation.

NON-CLINICAL TESTING / PERFORMANCE DATA

Non-clinical testing of the Nucleoss T6 Implant System was performed following the FDA guidance: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments, and applicable ISO and ASTM standards.

Bench Testing

The Pull-out test was performed to compare the Nucleoss T6 Implant and reference device in accordance with ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws with acceptable test results. A comparative surface area analysis was conducted on the Nucleoss T6 Implant and reference device with the original length and 3mm bone loss.

Fatigue Testing

Fatigue testing conducted in accordance with ISO 14801:2016 Dentistry- Implants-Dynamic Fatigue Test for Endosseous Dental Implants found the durability of the Nucleoss T6 Implant and Abutment combinations was acceptable. Testing was conducted on the worst-case implant abutment combinations.

Sterilization Validation

Nucleoss T6 Implants are sterilized using a gamma ray sterilization process that has been validated in accordance with ISO 11137-2 Sterilization of healthcare products-Radiation-Part 2 establishing the sterilization dose to ensure a SAL of 10^{-6}.

Nucleoss Dental Abutments are provided non-sterile for end-user steam sterilization using a traditional cycle process. Since the raw material, production process, parameters and process materials of both Tpure and the predicate device are exactly same, the same steam sterilization parameters apply to the T6 Dental abutments as was used in the predicate device.

Accelerated Aging Test and Packaging Validation Test

Nucleoss T6 implants will be packaged and labeled based on new testing that was conducted to support a shelf life of 5 years on the predicate device. Package Validation and Simulated transportation testing on the predicate device that was accelerated aged to an equivalent 5 years found that the sterility of the dental implants was maintained.

Accelerated aging and packaging validation testing was not repeated for the T6 Dental Implants since the raw material, production process, parameters, process materials and all packaging materials/type of the T6 Dental Implants are exactly same as those of the predicate device.

Biocompatibility

All the materials used the T6 Dental Implant and the manufacturing processes were identical to those used in the predicate device.

Biocompatibility testing was not repeated for the T6 Dental Implants since the raw material, production process, parameters and process materials of the T6 Dental Implants and abutments and the predicate device are exactly the same.

CONCLUSION

Data presented in this 510(k) Submission support the substantial equivalence of the T6 Dental Implant to the predicate devices. The Nucleoss T6 Dental Implant System have the similar indication for use, material composition, design, and surface treatment to the primary predicate device and reference predicate devices. Based on the comparative assessment including minor differences with the predicate devices, and based on performance test data, the Nucleoss T6 Dental Implant System is determined to be substantially equivalent to the predicate devices.