DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 4, 2017

Sanlilar Tibbi Cihazlar Medikal Kimya Sanayi Ticaret Limited Sirketi
% H. Semih Oktay, PhD
President
CardioMed Device Consultants, LLC
1783 Forest Drive, #254
Annapolis, Maryland 21401

Re: K160850
Trade/Device Name: Nucleoss Tpure Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 4, 2017
Received: July 6, 2017

Dear H. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K160850

Device Name
Nucleoss Tpure Implant System

Indications for Use *(Describe)*
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.

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

Premarket Notification 510(k) Summary

I. SUBMITTER

Submitter's Name: Sanlilar Tibbi Cihazlar Medikal Kimya Sanayi Ticaret Limited Sirketi
Address: 10018 Sok. No 7 ITOB Organize Sanayi Bolgesi Tekeli, Izmir TR-35477
Turkey
Telephone: 90-232-799 0304
Fax Number: 90-232-799 0306
Contact Person: Ezgi OZBUDAK

US Consultant: CardioMed Device Consultants
Address: 1783 Forest Drive, #254
Annapolis, MD 21401
Telephone: 410- 674-2060
Email: soktay@cardiomedllc.com
Contact Person: H. Semih Oktay. President

Date of Summary: August 4, 2017

II. DEVICE

Trade Name: Nucleoss Tpure Implant System
Common Name: Endosseous Dental Implant & Abutments
Product Codes: DZE (Primary Product Code), NHA
Regulatory Class: II
Classification name: 21 CFR 872.3640 Endosseous Dental implant

III. PREDICATE DEVICE

Primary Predicate device: Straumann Bone Level Tapered Implants - K140878

Reference Predicate devices:
Klockner Dental Implant Abutments (II) - K151194
Klockner Dental Implant Abutments - K122988
Zimmer Zfx Titanium Abutment for Biomet 3i Certain Implant System - K141544
Straumann Sterile Healing Solution - K161677

IV. DEVICE DESCRIPTION

The Nucleoss Tpure Implant System consists of the Nucleoss Tpure Dental Implant, Nucleoss Dental Abutments, Covers, Gingiva Formers, Comfort Caps, and accessories.

The Nucleoss Tpure Implant is a bone level, root form implant constructed of unalloyed titanium per ISO 5832-2, with an SLA surface treatment. Nucleoss Tpure Implants have a conical form design, with a double lead thread form and two vertical anti-rotation grooves. The internal structure is designed as a conical internal hex connection with 80 degree bevel.

Nucleoss Tpure Implants are provided in the following sizes: 3.4 mm diameter with lengths of 10, 12 and 14 mm, and 3.8, 4.2, 5.0 mm diameters with lengths of 8, 10, 12, and 14 mm.

Nucleoss Dental Abutments are constructed of titanium alloy per ISO 5832-3and are intended for cement-retained and screw-retained restorations. An internal hexagon allows connection to the Nucleoss Tpure implant. Nucleoss Dental Abutments are available in Straight, Angled, Multi-unit, Ball and Equator designs. The Angled abutment is provided in angles of 10, 20 and 30 degrees. The Multi-unit abutment is available in a straight design, and angled designs of 17 and 30 degrees. Nucleoss Covers, Comfort Cap and Gingiva Formers are available for use during the healing period following surgical placement of the implant. The Nucleoss Tpure Implant System also includes metal housings combined with caps to provide a secure coupling for the denture prosthetic attachment to the Ball and Equator abutments.

All of the Nucleoss Tpure Implant System components are single-use devices. The Nucleoss Tpure Implant and related Cover is provided sterile. The Nucleoss Abutments and accessories are provided nonsterile for end-user sterilization.

V. INDICATIONS FOR USE

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.

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the Nucleoss Tpure Implant System was compared to the predicate devices to determine substantial equivalence. The Nucleoss Tpure Dental Implant, Nucleoss Dental Abutments, Cover, Gingiva Former and Comfort Cap, have a similiar indication for use, material composition, surface treatment and design as the predicate devices.

The Nucleoss Tpure Dental Implant indication for use differs from the predicate Straumann Bone Level Tapered Implants (K140878) in that the Nucleoss Tpure Dental Implant is intended for delayed loading only, and is not restricted to four implants in edentulous patients. These differences do not raise new concerns because limiting the use of the dental implant to delayed loading is a more conservative surgical approach, and the use of fewer implants for a tissue-supported overdenture is a standard clinical protocol.

Similarly, differences in the Indication for Use of the Nucleoss Abutment System and the predicates [Klockner Dental Implant Abutments (K151194 and K122988), and Zimmer Zfx Titanium Abutment for Biomet 3i Certain Implant System (K141544)] do not affect substantial equivalence because each of the abutments are intended for use with specific dental implants for the purpose of providing support for prosthetic reconstructions.

The Nucleoss Tpure Dental Implant with a maximum implant diameter of 5.0mm differs from the predicate, Straumann Bone Level Tapered Implants (K140878) maximum implant diameter of 4.8 mm. This difference is compatible with the variation in anatomical sizes of the human jaw bone, and does not present a worst-case scenario for the device.

The Nucleoss Straight and Angled Abutment designs are for single or multiple cement retained restorations, whereas the predicate Klockner Dental Implant Abutments (K151194 and K122988) are only for multiple screw retained restorations.

The Nucleoss Multi-unit Abutment differs from the Klockner Dental Implant Abutments (K151194 and K122988) abutments for multiple and single restorations with respect to connection type. The Nucleoss Multi-unit Abutments have internal hex connection, while the Klockner abutmnts have internal cone connection. Performance testing of the Nucleoss Dental Implant combined with the Nucleoss Multi-unit Abutment demonstrated substantial equivalence of the connection platform design.

The Nucleoss Abutment platform diameter range (4.2mm – 6.0mm) differs from that of the predicate Zimmer Zfx Titanium Abutment for Biomet 3i Certain Implant System (K141544) which has platform diameters of 3.4 mm to 6.0mm.

The Nucleoss Tpure Implant System also offers an additional overdenture abutment design, the Equator Abutment. The Equator Abutment provides a different connection design for the denture but does not change the intended use of supporting a denture restoration.

The Gingiva Former and Cover differs from the predicate, Straumann Sterile Healing Solution (K161677) with respect to additional platform diameter sizes. The additional platform sizes are provided so as to accomodate the Nucleoss Dental Implant.

Substantial Equivalence Comparison – Nucleoss Tpure Dental Implant

Technological Characteristics	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Nucleoss Tpure Dental Implant	**Straumann Bone Level Tapered Implants (K140878)**
Indications for Use	Indicated for surgical placement 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. Nucleoss Abutments and Prosthetic parts are intended for use with Nucleoss Tpure Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdenture for edentulous or partially edentulous patients	Indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used 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 by the corresponding elements (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
Material	Grade 4 commercially pure titanium conforming with ISO 5832-2	Grade 4 commercially pure titanium conforming with ISO 5832- 2
Surface Treatment	Sand blasted Large grit Acid etched (SLA)	Sand blasted Large grit Acid etched (SLA)
Design	Two component / Bone level/Conical form Two stage surgical technique For single or multiple restorations Tpure Implant threads are designed in double lead thread form with two vertical anti-rotation grooves. Constant major and minor thread diameters (i.e., parallel wall) 0.75mm thread pitch. Angled major and minor thread diameters (i.e., tapered wall), with the major and minor diameters have differing angles such that the depth increases toward the apical end of the implant and the addition of cutting flutes 0.75mm thread pitch.	Two component / Bone level/Conical form Two stage surgical technique For single or multiple restorations Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch. Angled major and minor thread diameters (i.e., tapered wall), with the major and minor diameters have differing angles such that the depth increases toward the apical end of the implant and the addition of cutting flutes 0.8mm thread pitch.

	The internal structure is designed as a conical internal hex connection with 80 degrees.	
Transfer piece	Fixture-mount transfer part, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.	Snap fit mount Loxim™ transfer piece, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.
Diameter (mm)	3.4, 3.8, 4.2, 5.0	3.3, 4.1, 4.8
Length (mm)	8, 10, 12, 14	8, 10, 12, 14
Sterilization	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)

Substantial Equivalence Comparison - Nucleoss Dental Abutments

	SUBJECT DEVICE	**REFERENCE PREDICATE DEVICE**	**REFERENCE PREDICATE DEVICE**	**REFERENCE PREDICATE DEVICE**
	Nucleoss Abutment System	**Klockner Dental Implant Abutments (II) (K151194)**	**Klockner Dental Implant Abutments (K122988)**	**Zimmer Zfx Titanium Abutment for Biomet 3i Certain Implant System (K141544)**
Material	Titanium alloy	Titanium alloy Gold alloy & Co-Cr-Mo alloy (for Cast abutment)	Titanium Alloy	Titanium alloy
Abutment Design	Straight and Angled (10-30^0): For single or multiple cement retained restorations Internal hex connection. Multi-unit: For multiple screw-retained restorations Internal hex connection Equator and Ball: For overdenture restorations Internal hex connection	Straight and Angled (10-30°): For multiple-unit screw-retained restorations Internal octagonal cone connection Cast: For single or multiple-unit cement-retained restorations Temporary: For multiple-unit screw-retained restorations	Straight and Angled (10-30°): For multiple-unit screw-retained restorations internal octagonal & external hexagonal connection system Temporary: For multiple-unit screw-retained restorations Overdenture:Screw-retained Ball attachment design	Patient-Specific: abutment For single or multiple screw-retained restorations Angled Abutments (10-30°) Internal hex connection
Abutment Platform Diameter (mm)	Straight & Angled: 4.2, 5.0 6.0 Ball: 4.5 Multi-unit: 5.0 mm	Not known	Standard and wide platform	3.4, 4.1, 5.0 and 6.0
Abutment	Straight: 1.0, 2.0, 3.0, 5.0	Straight:	Not known	Not known

Platform Heights (mm)	Angled: 1.0, 2.0, 3.0, 4.0 Multi-unit: 0^0: 1.5, 3.0, 5.0 17°:1.5-3.1 & 2.4-4.0 30°:1.25-4.0 & 2.0 - 4.75 Ball & Equator: 1.5, 3.0, 5.0	1.0, 2.5 & 4.0 Angled: 2.0, 3.0, 4.0 & 5.0		
Sterilization	Provided non-sterile	Provided non-sterile	Not known	Provided non-sterile

Substantial Equivalence Comparison – Nucleoss Gingiva Former and Cover

Technological Characteristics	**SUBJECT DEVICE**	**REFERENCE PREDICATE DEVICE**
	Nucleoss Gingiva Former and Cover	Straumann Sterile Healing Solution (K161677)
Material	Titanium alloy per ISO 5832-3	Pure Titanium (grade 4) per ISO 5832-2
Design	The Cover and Gingiva Former are screwed on the implant to cover the implant. Gingiva Former and Cover are color coded according to their platform diameter.	The devices are available in one and two-piece assemblies, and in various diameters and heights. Healing abutment, closure cap and closure screw are color coded; yellow and purple.
Platform Diameter (mm)	Gingiva Former: 4.2, 5.0, 6.0 Cover: 4.2, 5.0, 6.0	Healing abutment: 4.5, 6.0
Platform Heights (mm)	Gingiva Former: 2.0, 4.0, 6.0 Cover: 0	Healing abutment: 2.0, 4.0, 6.0 Closure cap: 0, 1.5, Closure screw: 0, 0.5
Sterilization	Cover: Gamma irradiation (with implant). Gingiva Former: provided non-sterile.	Provided sterile via Gamma Irradiation

VII. PERFORMANCE DATA

Non-clinical testing of the Nucleoss Tpure 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.

Biocompatibility

Cytotoxicity
Manufacturing Process FMEA Risk Analysis
SEM & Energy Dispersive X-ray Spectroscopy (EDX) Implant Surface Study
Chemical Analysis of Implant Surface

The test results and analyses found that the dental implant material and manufacturing processes were biocompatible.

Fatigue Testing

Fatigue testing, conducted in accordance with ISO 14801:2007 Dentistry- Implants-Dynamic Fatigue Test for Endosseous Dental Implants found the durability of the Nucleoss Tpure Implant and Abutment combinations was acceptable. Testing was conducted on the worst case implant abutment combinations.

MRI Safety

Nucleoss Dental Implant Systems were found to be MR Conditional following testing in accordance with ASTM: F 2052-14 Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment, ASTM F2182–11a Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, and ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

Sterilization Validation

Nucleoss Tpure 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}. LAL testing was conducted according to USP 85 and the FDA Guidance “Submission and Review of Sterility information in Premarket Notification 510k Submissions for Devices Labeled as Sterile." Shelf life testing was conducted according to ASTM D4169-16, ASTM F1980-16, ASTM F1929-15, ASTM D5276-98, and ASTM F88/F88M-15.

Nucleoss Dental Abutments are provided non-sterile for end-user steam sterilization using a traditional cycle process as identified in the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. The recommended end user steam sterilization parameters were validated in accordance with ISO 17665-1:2006 and ISO 17665-2 2009.

VIII. CONCLUSION

The Nucleoss Tpure Dental Implant System have the same or similar intended use, material composition, design, and surface treatment. Based on an a comparative assessment with the predicate devices, and the performance test data, the Nucleoss Tpure Dental Implant System is determined to be substantially equivalent to the predicate devices.