Z7 LLC
% Linda Braddon
Chief Executive Officer
Secure BioMed Evaluations
7828 Hickory Flat Highway
Suite 120
Woodstock, Georgia 30188

June 26, 2023

Re: K221488
Trade/Device Name: Z7 Zirconia Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 25, 2023
Received: May 25, 2023

Dear Linda Braddon:

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,

Andrew I. Steen -S

Andrew I. 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)*

K221488

Device Name
Z7 Zirconia Implant System

Indications for Use *(Describe)*

The Z7 Zirconia Implant System is intended for surgical placement in the patient's upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The ø3.7 mm reduced diameter implants are recommended for central and lateral incisors only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**K221488**
**510(k) SUMMARY**
Z7 Zirconia Implant System

| | |
|---|---|
| **Date Prepared** | June 26, 2023 |
| **Sponsor** | Z7, LLC<br>28 Felmley Road<br>Whitehouse Station, NJ<br>908-399-1359 |
| **510(k) Contact** | Secure BioMed Evaluations<br>Linda Braddon, Ph.D.<br>7828 Hickory Flat Highway<br>Suite 120<br>Woodstock, GA 30188<br>770-837-2681<br>Regulatory@SecureBME.com |
| **Trade Name** | Z7 Zirconia Implant System |
| **Common Name** | Endosseous Dental Implant |
| **Code – Classification** | DZE, NHA<br>21 CFR 872.3640: Class II |
| **Primary Predicate** | K192053 TAV Medical Ltd. W Zirconia Implants |
| **Reference Device** | K172668 TAV Medical Ltd. W Zirconia Implants<br>K132585 Zibone Ceramic Dental Implant System |
| **Device Description** | The Z7 Zirconia Implant System is an integrated system of endosseous dental implants (Z7 Zirconia Implant One Piece) and PEEK prosthetic parts. The Z7 Zirconia Implant One Piece are yttria stabilized tetragonal zirconia (Y-TZP) dental implants composed of a One Piece, monotype implant with an integrated abutment. The implant is manufactured via a ceramic injection molding with the macro and micro surface characteristics of the implant directly structured in the mold. The implant body portion is configured to extend into the bone and osseo-integrate with the alveolar bone. The neck should be positioned 1.8mm above the bone. The implants come in corresponding diameters of 3.7 and 4.3 mm. |
| **Indications for Use Statement** | The Z7 Zirconia Implant System is intended for surgical placement in the patient's upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.<br><br>The Ø3.7mm reduced diameter implants are recommended for central and lateral incisors only. |

**Comparison of Indications for Use**

| Subject Device<br>Z7 Zirconia Implant System | Primary Predicate Device<br>TAV Medical's W Zirconia Implants<br>K192053 |
|---|---|
| Intended for surgical placement in the patient's upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.<br><br>The ø3.7 mm reduced diameter implants are recommended for central and lateral incisors only. | Intended for surgical placement in the patient's upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading<br><br>The ø3.6 mm reduced diameter implants are recommended for central and lateral incisors only. |

There are no significant differences between the subject and predicate device indications for use. The minor differences in wording to align with the provided sizes of the subject device do not change the intended use for demonstration of substantial equivalence.

**Comparison of Technological Characteristics - Implants**

| Characteristic | Subject Device<br>Z7 Zirconia Implant System | Primary Predicate Device<br>TAV Medical's W Zirconia Implants<br>K192053 | Reference Device<br>TAV Medical's W Zirconia Implants<br>K172668 |
|---|---|---|---|
| Purpose of Device | Subject Device | Same Indications | Similar One-Piece Sizes as Subject Device |
| Device Classification | Class II | Class II | Class II |
| Product Code | DZE, NHA | DZE, NHA | DZE, NHA |
| Material | Yttria-stabilized zirconia (Y-TZP) per ISO 13356:2015 | Yttria-stabilized zirconia (Y-TZP) per ISO 13356:2015 | Yttria-stabilized zirconia (Y-TZP) per ISO 13356:2015 |
| Surface Topography | Macro and Micro Roughness | Macro and Micro Roughness | Macro and Micro Roughness |
| Description | Endosseous dental implant | Endosseous dental implant | Endosseous dental implant |
| Design | One-Piece Ceramic Implants | One-Piece Ceramic Implants | One-Piece Ceramic Implants |
| | N/A | Two-Piece Ceramic Implants | Two-Piece Ceramic Implants |
| Diameter | Z7 One-Piece: 3.7mm, 4.3mm | TAV W One-Piece: 3.6mm | TAV W One-Piece: 4.1mm, 4.8mm |

| Characteristic | Subject Device Z7 Zirconia Implant System | Primary Predicate Device TAV Medical's W Zirconia Implants K192053 | Reference Device TAV Medical's W Zirconia Implants K172668 |
|---|---|---|---|
| | N/A | TAV W Two-Piece: 4.1mm, 4.8mm | TAV W Two-Piece: 4.1mm, 4.8mm |
| Length | Z7 One-Piece: 10mm, 13mm | TAV W One-Piece: 8mm, 10mm, 12mm, 14mm | TAV W One-Piece: 8mm, 10mm, 12mm, 14mm |
| | N/A | TAV W Two Piece: 8mm, 10mm, 12mm, 14mm | TAV W Two Piece: 8mm, 10mm, 12mm, 14mm |
| Manufacturing Technology | CIM: Ceramic injection molding | CIM: Ceramic injection molding | CIM: Ceramic injection molding |
| Sterilization Method | Ethylene Oxide | Gamma irradiation | Gamma irradiation |
| Intended Use Environment | Dental clinic setting | Dental clinic setting | Dental clinic setting |
| Abutments | Straight | TAV W One-Piece: Straight | TAV W One-Piece: Straight |
| | N/A | TAV W Two-Piece: Straight and Angled | TAV W Two-Piece: Straight and Angled |
| Biocompatibility | Implant device with permanent (>30 days) contact with tissue / bone / dentin | Implant device with permanent (>30 days) contact with tissue / bone / dentin | Implant device with permanent (>30 days) contact with tissue / bone / dentin |
| Shelf-Life | 5 years | Not stated in 510(k) Summary | 1 year |

**Comparison of Technological Characteristics – PEEK Healing Caps**

| Characteristic | Subject Device MABB Z7 Zirconia Implant System | Primary Predicate Device TAV Medical's W Zirconia Implants K192053 | Reference Device TAV Medical's W Zirconia Implants K172668 |
|---|---|---|---|
| **Regulation Number** | 872.3640 | 872.3640 | 872.3640 |
| **Classification Product Code** | DZE, NHA | DZE, NHA | DZE, NHA |
| **Product Name** | PEEK Healing Cap | PEEK Healing Cap for W One Piece Zirconia Implant | PEEK Healing Cap for W One Piece Zirconia Implant |
| **Product Description** | Protect the implant during the healing phase up to 180 days. | Protect the implant during the healing phase up to 180 days. | Protect the implant during the healing phase up to 180 days. |

| Characteristic | Subject Device MABB Z7 Zirconia Implant System | Primary Predicate Device TAV Medical's W Zirconia Implants K192053 | Reference Device TAV Medical's W Zirconia Implants K172668 |
|---|---|---|---|
| **Material** | PEEK per ASTM F2026-17 | PEEK | PEEK |
| **Diameter (mm)** | 3.7, 4.3 | 3.6, 4.1, 4.8 | 4.1, 4.8 |
| **Height (mm)** | 5 | 5 | 5 |
| **Angle (°)** | 0° (Straight) | 0° (Straight) | 0° (Straight) |
| **Sterility** | Non-Sterile | Non-Sterile | Non-Sterile |

**Comparison of Technological Characteristics – PEEK Temporary Abutments**

| Characteristic | Subject Device MABB Z7 Zirconia Implant System | Primary Predicate Device TAV Medical's W Zirconia Implants K192053 | Reference Device TAV Medical's W Zirconia Implants K172668 |
|---|---|---|---|
| **Regulation Number** | 872.3640 | 872.3640 | 872.3640 |
| **Classification Product Code** | DZE, NHA | DZE, NHA | DZE, NHA |
| **Product Name** | PEEK Healing Cap | PEEK Healing Cap for W One Piece Zirconia Implant | PEEK Healing Cap for W One Piece Zirconia Implant |
| **Product Description** | Serves as a basis for temporary restoration for crown. Up to 180 days. | Serves as a basis for temporary restoration for crown or bridge. Up to 180 days. | Serves as a basis for temporary restoration for crown or bridge. Up to 180 days. |
| **Material** | PEEK per ASTM F2026-17 | PEEK | PEEK |
| **Diameter (mm)** | 3.7, 4.3 | 3.6, 4.1, 4.8 | 4.1, 4.8 |
| **Angle (°)** | 0° (Straight) | 0° (Straight) | 0° (Straight) |
| **Sterility** | Non-Sterile | Non-Sterile | Non-Sterile |

**Technological Characteristics**

There are no significant technological differences between the subject and predicate devices. Minor differences include the method of sterilization, and the exact size offerings. The subject device uses the same material as the additional predicates and all devices are manufactured using ceramic injection molding techniques. Any technological differences between the subject and predicate devices do not raise new concerns for safety or effectiveness.

**Non-Clinical Performance Testing Summary**

Performance testing for the subject device is summarized in the table below:

| Test | Test Method Summary | Results |
|---|---|---|
| Material Performance Testing | Per ISO 13356:2015 Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) | **PASS**<br><br>Device met all predetermined acceptance criteria |
| Fatigue Testing | Per ISO 14801:2016 Dentistry — Implants — Dynamic loading test for endosseous dental implants | **PASS**<br><br>Substantially equivalent fatigue strength to reference device (K132585) |
| Implant Surface Roughness and Chemical Analysis Validation | Surfaces macro and micro morphological characterization through 3D Scanning Electron Microscope (SEM) Imaging. Surface chemical analysis through Energy Dispersive Spectrometry (EDS Analysis). | **PASS**<br><br>Device met all predetermined acceptance criteria |

Biological evaluation of the subject device was performed according to ISO 10993-1 (cytotoxicity testing per ISO 10993-5). Endotoxin testing on the subject device or suitable test specimens was performed following USP<85> and USP<161> according to the sponsor's endotoxin sampling plan.

The implants are provided sterile to the end user via Ethylene Oxide (EO) sterilization. The applicable cycle was validated in compliance with ISO 11135:2014 "Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices" to a sterility assurance level of $10^{-6}$ for the worst-case configuration of the subject device. All cycle parameters were within the limits established by the protocol and residue testing yielded acceptable results for EO and ECH (ethylene chlorohydrin) per ISO 10993-7:2008 "Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals". The subject device non-sterile components are end-user steam sterilized. The applicable steam sterilization cycle was validated in compliance with ISO 17665 "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 demonstrated a sterility assurance level of $10^{-6.}$

Accelerated aging has been applied on the final sterile implant packaging and is being followed by real time aging to validate a five-year shelf life.

## Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.