Zentek Medical LLC
℅ Carlos Marín
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

October 15, 2025

Re: K251294
Trade/Device Name: Bonafix Implant Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 11, 2025
Received: September 11, 2025

Dear Carlos Marín:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251294

Device Name
Bonafix Implant Abutments

Indications for Use *(Describe)*
Bonafix Implant Abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Compatible Implant Systems

| Dental implant System | Implant Body Diameter (mm) | Platform Diameter |
|---|---|---|
| Neodent GM | 3.5, 3.75, 4.0, 4.3, 5.0 | Single Platform |
| Nobel Replace | 3.5 | NP |
| | 4.3 | RP |
| | 5.0 | WP |
| Biomed 3I Certain | 3.4 | 3.4 |
| | 4.1 | 4.1 |
| | 5.0 | 5.0 |
| Straumann Tissue Level | 4.1, 4.8 | RN |
| | 4.8 | WN |
| Astratech | 3.5, 4.0 | Small |
| | 4.5, 5.0 | Large |
| Straumann BLX | 3.5, 3.75, 4.0, 4.5 | RB |
| Megagen AnyRidge | 4.0, 4.4 | Regular |
| | 4.9, 5.4, 5.9 | Wide |
| Megagen AnyOne | 3.9 | 3.5 |
| | 4.3, 4.8, 5.3, 6.3 | 3.9 |

All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.

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
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*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
# K251294

Prepared October 15, 2025

## I) Applicant

| | |
|---|---|
| Submitter | ZENTEK MEDICAL LLC |
| Address | 200 Craig Rd Ste 107<br>Manalapan, NJ 077268735 |
| Contact | Michael Vinnik<br>Owner |
| Telephone | +1 732-2840545 |
| E-mail | mvinnik2@gmail.com |

## II) Consultant

| | |
|---|---|
| Company | COMPLIANCE 4 DEVICES |
| Address | 118 W Prive Cr.<br>Delray Beach FL, 33445 |
| Contact | Carlos Marín<br>Juan Tezak |
| Telephone | +1 561-7892411 |
| E-mail | compliance4devices@gmail.com |

## III) Device

| | |
|---|---|
| Trade Name | Bonafix Implant Abutments |
| Common Name | Dental Implant Abutment |
| Classification Name | Endosseous dental implant abutment |
| Regulation Number | 872.3630 |
| Product Code | NHA |

## IV) Predicate Device

| | |
|---|---|
| 510(k) Number | K221673 |
| Applicant | ZENTEK MEDICAL LLC |
| Trade Name | Bonafix TiBase |
| Classification Name | Endosseous dental implant abutment |
| Regulation Number | 872.3630 |
| Product Code | NHA |

## V) Reference Device

| | |
|---|---|
| 510(k) Number | K240570 |
| Applicant | IMPLANT PROTESIS DENTAL 2004, S.L |
| Trade Name | IPD DENTAL IMPLANT ABUTMENTS |
| Classification Name | Endosseous dental implant abutment |
| Regulation Number | 872.3630 |
| Product Code | NHA |

VI) Reference Device

| | |
|---|---|
| 510(k) Number | K242819 |
| Applicant | IMPLANT PROTESIS DENTAL 2004, S.L |
| Trade Name | IPD DENTAL IMPLANT ABUTMENTS |
| Classification Name | Endosseous dental implant abutment |
| Regulation Number | 872.3630 |
| Product Code | NHA |

Additional Reference Devices for Compatible Implants:

| Compatible Implant System | Implant Body Diameter (mm) | Implant Platform Diameter (mm) | K Number |
|---|---|---|---|
| Neodent GM | 3.5, 3.75, 4.0, 4.3, 5.0 | Single Platform | K163194 |
| Nobel Replace | 3.5 | NP | K073142 |
| | 4.3 | RP | K073142 |
| | 5.0 | WP | K073142 |
| Biomed 3I Certain | 3.4 | 3.4 | K063341 |
| | 4.1 | 4.1 | K063341 |
| | 5.0 | 5.0 | K130222 |
| Straumann Tissue Level | 4.1, 4.8 | RN | K101732 and K120414 |
| | 4.8 | WN | K120414 |
| Astratech | 3.5, 4.0 | Small | K191256 |
| | 4.5, 5.0 | Large | K181703 |
| Straumann BLX | 3.5, 3.75, 4.0, 4.5 | RB | K173961 |
| Megagen Anyridge | 4.0, 4.4 | Regular | K140091 |
| | 4.9, 5.4, 5.9 | Wide | |
| Megagen Anyone | 3.9 | 3.5 | K123988 |
| | 4.3, 4.8, 5.3, 6.3 | 3.9 | |

VII) Indication For Use

Bonafix Implant Abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

| Compatible Implant System | Implant Body Diameter (mm) | Implant Platform Diameter (mm) |
|---|---|---|
| Neodent GM | 3.5, 3.75, 4.0, 4.3, 5.0 | Single Platform |
| Nobel Replace | 3.5 | NP |
| | 4.3 | RP |
| | 5.0 | WP |
| Biomed 3I Certain | 3.4 | 3.4 |
| | 4.1 | 4.1 |
| | 5.0 | 5.0 |
| Straumann Tissue Level | 4.1, 4.8 | RN |

| Compatible Implant System | Implant Body Diameter (mm) | Implant Platform Diameter (mm) |
|---|---|---|
| | 4.8 | WN |
| Astratech | 3.5, 4.0 | Small |
| | 4.5, 5.0 | Large |
| Straumann BLX | 3.5, 3.75, 4.0, 4.5 | RB |
| Megagen Anyridge | 4.0, 4.4 | Regular |
| | 4.9, 5.4, 5.9 | Wide |
| Megagen Anyone | 3.9 | 3.5 |
| | 4.3, 4.8, 5.3, 6.3 | 3.9 |

All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.

VIII) Device Description

Bonafix Abutment Solutions are a dental implant abutments system that includes three abutment design types (Temporary, Straight Ti-Base and Multi-Unit), that can be used to support single-unit or multi-unit prosthetic restorations. These abutments incorporating interface features compatible with sixteen (16) endosseous dental implant system platforms (Eight (8) designs from five (5) manufactures). The subject device abutments platform diameters range from 3.5mm to 6.3mm, and the corresponding compatible implant body diameters also range from 3.5 mm to 6.3mm. The system also includes corresponding abutment screws.

**Temporary Abutments**

Are manufactured from Titanium Grade 5 and consist of a coronal section, a platform and a connection part. The abutments are provided non-sterile with instructions for end user sterilization. The Temporary Abutments are seated in the implant with a prosthetic screw which is also manufactured from Titanium Grade 5. The prosthetic screw is delivered with the abutment. Angular correction of temporary abutments and placement of implant bodies at an angle is not allowed, they must be used parallel to the direction of occlusal loading forces.

Temporary Abutments can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Modifications can be made by the end-user only in the minimum post height.

- Minimum post height – 4.0 mm

Temporary Abutments have a maximum duration of usage of 180 days.

They are available in the following sizes:

| Systems | Platform | Characteristic |
|---|---|---|
| NEODENT GM | Single platform | Engaging |
| | | Non-Engaging |
| NOBEL REPLACE | NP | Engaging |
| | | Non-Engaging |
| | RP | Engaging |
| | | Non-Engaging |
| | WP | Engaging |
| | | Non-Engaging |
| Biomed 3I Certain | 3.4 | Engaging |
| | | Non-Engaging |
| | 4.1 | Engaging |
| | | Non-Engaging |
| | 5.0 | Engaging |
| Straumann Tissue Level | RN | Engaging |
| | | Non-Engaging |
| | WN | Engaging |
| | | Non-Engaging |
| Straumann BLX | RB | Engaging |
| | | Non-Engaging |
| Megagen Anyone | 3.9 | Engaging |
| | | Non-Engaging |
| | 4.3, 4.8, 5.3, 6.3 | Engaging |
| | | Non-Engaging |

**Ti-base Abutments**

The Bonafix TiBase abutment is composed of two-piece abutment that is a titanium base at the bottom and a zirconia superstructure (CAD/CAM patient specific superstructure) at the top. The superstructure are fabricated using a CAD/CAM process in Zirconia. The apical end is prefabricated to fit the compatible implant platform, as shown above, and is available with implant connections for crowns (with socket) or bridges (without socket).

Angular correction of abutments and placement of implant bodies at an angle is not allowed, they must be used parallel to the direction of occlusal loading forces.

Each abutment is provided with a screw designed to fit the compatible implant.

The design parameters for the fabrication of the zirconia superstructure, which are already locked in the CAD/CAM software, are as follows:

- Minimum wall thickness – 0.45 mm
- Minimum abutment post height – 4.0 mm
- Maximum abutment post height – 6.5mm
- Maximum gingival height – 5.0 mm
- Minimum gingival height – 0.7 mm
- Angulation – 0°

Note: The abutment post height is defined as the portion of the abutment above the gingival height.

All digitally designed superstructures, and/or hybrid crowns for use with Bonafix TiBase abutments are to be sent to a Zentek validated milling center for manufacture. All superstructures are to be manufactured from zirconia conforming to ISO 13356.

All potential foreign machining center candidates must comply with a quality selection process in which they must meet the following characteristics:

- Must be registered with the FDA as a medical device manufacturer.
- Must have a quality system in place under CFR 820.
- Pass the manufacturing validation tests, which guarantee that the designs elaborated in the program (EXOCAD) are replicated correctly and accurately by the machines used by the supplier.

After passing the validation tests, the manufacturer may be registered within the ZENTEK quality system as a validated supplier for the fabrication of superstructures for ZENTEK Ti-base abutments.

The required cement for bonding the zirconia superstructure to the Bonafix TiBase abutments to create the final two-piece abutment is G-CEM LinkAce™ cleared in K120243

Bonafix Ti-Base Abutments are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) with the superstructure made of zirconia conforming to ISO 13356 Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).

They are available in the following sizes:

| Systems | Platform | Characteristic |
|---|---|---|
| NEODENT GM | Single platform | Engaging |
| | | Non-Engaging |
| NOBEL REPLACE | NP | Engaging |
| | | Non-Engaging |
| | RP | Engaging |
| | | Non-Engaging |
| Biomed 3I Certain | 3.4 | Engaging |
| | | Non-Engaging |
| | 4.1 | Engaging |
| | | Non-Engaging |
| | 5.0 | Engaging |
| | | Non-Engaging |
| Straumann Tissue Level | RN | Engaging |
| | | Non-Engaging |
| Astratech | Small | Engaging |
| | | Non-Engaging |
| | Large | Engaging |
| | | Non-Engaging |

| | | |
|---|---|---|
| Straumann BLX | RB | Engaging |
| | | Non-Engaging |
| Megagen Anyridge | 4.0, 4.4 | Engaging |
| | | Non-Engaging |
| | 4.9, 5.4, 5.9 | Engaging |
| | | Non-Engaging |
| Megagen Anyone | 3.9 | Engaging |
| | | Non-Engaging |
| | 4.3, 4.8, 5.3, 6.3 | Engaging |
| | | Non-Engaging |

**Multi-Unit Straight Abutments**

The Multi-unit abutments are screw-attached to the implant to restore fully or partially edentulous arches. Their use is not intended for single-unit crowns. They are designed with various gingival heights (1.5, 2.5 and 3.5mm) and can be screwed directly to a compatible implant. They use a titanium Multi-unit sleeve, which is cemented to the prosthesis. Together with a titanium prosthetic screw, the prosthesis is ready to be screwed onto the Multi-unit abutment, which in turn is screwed onto the implant, thus completing the restoration.

This multi-unit abutments are not intended to provide angle or divergence correction.

For all system, are manufactured from Titanium Grade 5.

Multi-unit sleeve can only be modified in the post height and that the minimum post height is 4mm from gingival collar.

They are available in the following sizes:

| Systems | Platform |
|---|---|
| NEODENT GM | Single platform |
| NOBEL REPLACE | NP |
| | RP |
| | WP |
| Biomed 3I Certain | 3.4 |
| | 4.1 |
| | 5.0 |
| Straumann Tissue Level | RN |
| | WN |
| Astratech | Small |
| | Large |
| Straumann BLX | RB |
| Megagen Anyridge | 4.0, 4.4 |
| | 4.9, 5.4, 5.9 |

Other Multi-unit prosthetic device

| Device | Platform |
|---|---|
| Titanium Sleeve for Multi-unit | Single platform |
| Screw for multi-unit | Single platform |

**Prosthetic screw**

It is used to seat all abutments for the system, included the temporary abutments and ti-bases, to the dental implant. They are provided along the prosthetic components, but they are also provided as standalone screws. The Abutment screws are manufactured from titanium alloy conforming to ASTM F136.

All system abutments are provided non-sterile with instructions for end user steam sterilization.

| Systems | Platform |
|---|---|
| NEODENT GM | Single platform |
| NOBEL REPLACE | NP |
| | RP |
| | WP |
| Biomed 3I Certain | 3.4 |
| | 4.1 |
| | 5.0 |
| Straumann Tissue Level | RN |
| | WN |
| Astratech | Small |
| | Large |
| Straumann BLX | RB |
| Megagen Anyridge | 4.0, 4.4 |
| | 4.9, 5.4, 5.9 |
| Megagen Anyone | 3.9 |
| | 4.3, 4.8, 5.3, 6.3 |

The subject devices are provided non-sterile and required to be sterilized.

All Bonafix TiBase abutments are packaged into PET bag.

IX) Comparison of Technological Characteristics

Zentek Medical LLC, submits the following information in this Premarket Notification (510k) to demonstrate that, for the purpose of FDA´s regulation of medical devices, Bonafix Implant Abutments are substantially equivalent in indications and design principles to the legally marketed predicate device and reference devices shown below.

Comparative tables of indications for use and relevant technological characteristics have been provided as follows.

*Table 1. Subject and Predicate devices indications for use comparison*

<table>
<tr><th></th><th>INDICATIONS FOR USE STATEMENTS</th></tr>
<tr><td>Subject Device</td><td>Bonafix Implant abutment<br>Zentek Medical LLC</td></tr>
<tr><td></td><td>Bonafix Implant Abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.
<table>
<tr><th>COMPATIBLE IMPLANT SYSTEM</th><th>IMPLANT BODY DIAMETER (mm)</th><th>IMPLANT PLATFORM DIAMETER (mm)</th></tr>
<tr><td>Neodent GM</td><td>3.5, 3.75, 4.0, 4.3, 5.0</td><td>Single Platform</td></tr>
<tr><td rowspan="3">Nobel Replace</td><td>3.5</td><td>NP</td></tr>
<tr><td>4.3</td><td>RP</td></tr>
<tr><td>5.0</td><td>WP</td></tr>
<tr><td rowspan="3">Biomed 3I Certain</td><td>3.4</td><td>3.4</td></tr>
<tr><td>4.1</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td rowspan="2">Straumann Tissue Level</td><td>4.1, 4.8</td><td>RN</td></tr>
<tr><td>4.8</td><td>WN</td></tr>
<tr><td rowspan="2">Astratech</td><td>3.5, 4.0</td><td>Small</td></tr>
<tr><td>4.5, 5.0</td><td>Large</td></tr>
<tr><td>Straumann BLX</td><td>3.5, 3.75, 4.0, 4.5</td><td>RB</td></tr>
<tr><td rowspan="2">Megagen Anyridge</td><td>4.0, 4.4</td><td>Regular</td></tr>
<tr><td>4.9, 5.4, 5.9</td><td>Wide</td></tr>
<tr><td rowspan="2">Megagen Anyone</td><td>3.9</td><td>3.5</td></tr>
<tr><td>4.3, 4.8, 5.3, 6.3</td><td>3.9</td></tr>
</table>
All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.</td></tr>
<tr><td>Predicate Device</td><td>Bonafix TiBase abutment (K221673)<br>Zentek Medical LLC</td></tr>
<tr><td></td><td>Bonafix TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.
<table>
<tr><th>COMPATIBLE IMPLANT SYSTEM</th><th>IMPLANT BODY DIAMETER (mm)</th><th>IMPLANT PLATFORM DIAMETER (mm)</th></tr>
<tr><td rowspan="2">HIOSSEN ET III</td><td>3.5</td><td>Mini</td></tr>
<tr><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular</td></tr>
<tr><td rowspan="2">Nobel Active</td><td>3.5</td><td>NP</td></tr>
<tr><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td rowspan="2">Straumann Bone Level</td><td>3.3</td><td>NC</td></tr>
<tr><td>4.1, 4.8</td><td>RC</td></tr>
<tr><td rowspan="3">Zimmer Screw-Vent/<br>Tapered Screw-Vent</td><td>3.3, 3.7, 4.1</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>6.0</td><td>5.7</td></tr>
<tr><td>Bonafix 2 Plus Implants</td><td>3.5, 3.75, 4.20, 5.0, 6.0</td><td>3.5</td></tr>
</table>
All digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.</td></tr>
</table>

| | INDICATIONS FOR USE STATEMENTS |
|---|---|
| | |
| **Reference Device** | IPD Dental Implant Abutments (K242819)<br>(Implant Protesis Dental 2004, SL) |

IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.

| Compatible Implant System | Implant Diameter (mm) | Platform Diameter |
|---|---|---|
| Astra Tech Implant System (Osseospeed®) | 3.0 | 3.0 |
| | 3.5/4.0 | 3.5/4.0 |
| | 4.5/5.0 | 4.5/5.0 |
| OsseoSpeed™ Plus | 3.6 | 3.6 |
| | 4.2 | 4.2 |
| BioHorizons Tapered Internal Implant System | 3.0 | 3.0 |
| | 3.4 | 3.0 |
| | 3.8 | 3.5 |
| | 4.6 | 4.5 |
| | 5.8 | 5.7 |
| 3i Osseotite® Certain® Dental Implants | 3.25 | 3.4 |
| | 4.0 | 4.1 |
| | 5.0 | 5.0 |
| 3i® Osseotite® Dental Implants | 3.25 | 3.4 |
| | 4.0 | 4.1 |
| | 5.0 | 5.0 |
| Straumann® BLX Implant System | 3.5 - 4.5 | RB |
| | 5.0 - 6.5 | WB |
| Straumann BLX Ø3.5 mm Implants | 3.5 | RB |
| Anyone™ Internal Implant System | 3.5 -8.0 | RP |
| Xpeed AnyRidge Internal Implant System | 3.5 -8.0 | RP |
| Conical Connection Implants (MIS® C1) | 3.75 | SP |
| | 4.2 | SP |
| MIS Internal Hex Dental Implant System (MIS® Seven®) | 3.30 | Narrow |
| | 3.75 | Standard |
| | 4.20 | Standard |
| | 5.0 | Wide |
| | 6.0 | Wide |
| Osstem Implant System | 3.0 | Mini |
| | 3.5 | Mini |
| | 4.0 - 7.0 | Regular |
| Neodent Implant System – GM Line | 3.5 – 7.0 | GM (Grand Morse) |
| Nobel Biocare® Brånemark System | 3.5 | NP (3.5 mm) |
| | 3.75/4.0 | RP (4.1 mm) |
| | 5.0 | WP (5.1 mm) |
| Nobel Biocare® Nobel Active® | 3.0 | 3.0 mm |
| | 3.5 | NP (3.5 mm) |
| | 4.3/5.0 | RP (4.3 mm) |
| Straumann® Tissue Level | 3.3/4.1/4.8 | RN (4.8 mm) |
| | 4.8 | WN (6.5 mm) |

| Compatible Implant System | Implant Diameter (mm) | Platform Diameter |
|---|---|---|
| Straumann® Bone Level | 3.3 | NC (3.3 mm) |
| | 4.1/4.8 | RC (4.1 mm) |
| Zimmer Tapered Screw-Vent® | 3.7/4.1 | 3.5 mm |
| | 4.7 | 4.5 mm |
| | 6.0 | 5.7 mm |

The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

<table>
<tr><th></th><th>INDICATIONS FOR USE STATEMENTS</th></tr>
<tr><td></td><td></td></tr>
<tr><td>Reference Device</td><td>IPD Dental Implant Abutments (K240570)<br>(Implant Protesis Dental 2004, SL)</td></tr>
<tr><td></td><td>IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.
<table>
<tr><th>Compatible Implant System</th><th>Implant Diameter (mm)</th><th>Platform Diameter</th></tr>
<tr><td rowspan="3">Astra Tech Implant System<br>(Osseospeed®)</td><td>3.0</td><td>3.0</td></tr>
<tr><td>3.5/4.0</td><td>3.5/4.0</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0</td></tr>
<tr><td rowspan="2">OsseoSpeed™ Plus</td><td>3.6</td><td>3.6</td></tr>
<tr><td>4.2</td><td>4.2</td></tr>
<tr><td rowspan="5">BioHorizons Tapered Internal Implant System</td><td>3.0</td><td>3.0</td></tr>
<tr><td>3.4</td><td>3.0</td></tr>
<tr><td>3.8</td><td>3.5</td></tr>
<tr><td>4.6</td><td>4.5</td></tr>
<tr><td>5.8</td><td>5.7</td></tr>
<tr><td rowspan="3">3i Osseotite® Certain® Dental Implants</td><td>3.25</td><td>3.4</td></tr>
<tr><td>4.0</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td rowspan="3">3i® Osseotite® Dental Implants</td><td>3.25</td><td>3.4</td></tr>
<tr><td>4.0</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td rowspan="2">Straumann® BLX Implant System</td><td>3.5 - 4.5</td><td>RB</td></tr>
<tr><td>5.0 - 6.5</td><td>WB</td></tr>
<tr><td>Straumann BLX Ø3.5 mm Implants</td><td>3.5</td><td>RB</td></tr>
<tr><td>Anyone™ Internal Implant System</td><td>3.5 -8.0</td><td>RP</td></tr>
<tr><td>Xpeed AnyRidge Internal Implant System</td><td>3.5 -8.0</td><td>RP</td></tr>
<tr><td rowspan="2">Conical Connection Implants<br>(MIS® C1)</td><td>3.75</td><td>SP</td></tr>
<tr><td>4.2</td><td>SP</td></tr>
<tr><td rowspan="5">MIS Internal Hex Dental Implant System<br>(MIS® Seven®)</td><td>3.30</td><td>Narrow</td></tr>
<tr><td>3.75</td><td>Standard</td></tr>
<tr><td>4.20</td><td>Standard</td></tr>
<tr><td>5.0</td><td>Wide</td></tr>
<tr><td>6.0</td><td>Wide</td></tr>
<tr><td rowspan="3">Osstem Implant System</td><td>3.0</td><td>Mini</td></tr>
<tr><td>3.5</td><td>Mini</td></tr>
<tr><td>4.0 - 7.0</td><td>Regular</td></tr>
</table>
The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.</td></tr>
</table>

The indications for use of subject device in comparison with primary predicate device are verbatim, with the exception of the new implant systems which Bonafix Implant abutments is claiming compatibility for this submission. Further than this, no change in the intended use or indications for use of the Bonafix Implant Abutments has been carried out. The devices are specifically indicated for patients undergoing oral implant surgery to provide support for dental prosthetic restorations.

Similarly, for the subject device and primary predicate device, all digitally designed superstructures, and/or hybrid crowns for use with Titanium Base are to be sent to a Bonafix validated milling center for manufacture.

As previously referred, differences may be found in the list of compatible implant systems for subject and predicate devices. Compatibility of the subject abutments with the specific OEM implants is based on engineering and dimensional analysis.

Similarly, the whole set of compatible dental implant systems and their respective 510(k) have been also included in this submission as reference devices.

Despite this, no further differences are found in the device categories included for subject and predicate devices, and same approach is followed for finalizing the zirconia superstructures.

It is Zentek opinion that these differences do not affect the intended use of the subject device, and/or do not raise differences in terms of safety or efficacy.

*Table 2. Subject and Predicate devices technological characteristic comparison*

| COMPARISON | SUBJECT DEVICE | PREDICATE DEVICE | COMPARISON |
|---|---|---|---|
| **General Design Features** | | | |
| **Device** | Bonafix Implant Abutment<br>Zentek Medical LLC | Bonafix TiBase abutment<br>Zentek Medical LLC<br>(K221673) | |
| **Abutment Designs** | Temporary<br>Multi-Unit Straight<br>Titanium Base | Titanium Base | Similar |
| **Prosthesis Attachment** | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Same |
| **Restoration Type** | Single-unit (Crowns)<br>Multiple-unit (bridges) | Single-unit (Crowns)<br>Multiple-unit (bridges) | Same |
| **Abutment/Implant Platform Diameter (mm)** | 3.5 – 6.3 | 3.0 – 5.7 | Similar |
| **Abutment Angle** | Temporary (0°)<br>Multi-unit (0°)<br>Titanium Base (0°) | Titanium Base (0°) | Same |
| **Materials** | | | |
| **Abutment Metallic Material** | Ti-6Al-4V alloy (ASTM F136) | Titanium alloy, ASTM F136 | Same |
| **Screw** | Ti-6Al-4V alloy (ASTM F136) | Titanium alloy, ASTM F136 | Same |
| **Superstructure** | Zirconia (ISO 13356) | Zirconia | Same |
| **CAD/CAM Abutment Design Parameters** | | | |
| **Minimum abutment post height, mm** | 4.0 | 4.0 | Same |

| COMPARISON | SUBJECT DEVICE | PREDICATE DEVICE | COMPARISON |
|---|---|---|---|
| **Maximun abutment post heigth, mm** | 6.5 | 6.5 | Same |
| **Maximum gingival height, mm** | 5.0 | 5.0 | Same |
| **Minimum gingival height, mm** | 0.7 | 0.7 | Same |
| **Wall Minimum wall thickness** | 0.43 | 0.43 | Same |
| **Maximum abutment angulation** | 0° | 0° | Same |
| **Abutment attachment to implant** | Screw | Screw | Same |
| **Prosthesis attachment to abutment** | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Same |
| **Restoration** | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Same |
| **Abutment/ Implant Interface** | Internal connection | Internal connection | Same |
| **Sterilization** | | | |
| **Sterilization status and type** | Non-sterile<br>End user steam sterilization | Non-sterile<br>End user steam sterilization | Same |

*Table 3. Subject and Reference devices technological characteristic comparison (Multi-unit)*

| COMPARISON | SUBJECT DEVICE | REFERENCE DEVICE | COMPARISON |
|---|---|---|---|
| **General Design Features** | | | |
| **Device** | Bonafix Implant Abutment<br>Zentek Medical LLC | IPD Dental Implant Abutments<br>(Implant Protesis Dental 2004, SL)<br>(K242819) | |
| **Abutment Designs** | Temporary<br>Multi-Unit Straight<br>Titanium Base | Titanium Base<br>Multi-Unit<br>Overdenture | Similar |
| **Prosthesis Attachment** | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Same |
| **Restoration Type** | Single-unit (Crowns)<br>Multiple-unit (bridges) | Single-unit (Crowns)<br>Multiple-unit (bridges) | Same |
| **Abutment/Implant Platform Diameter (mm)** | 3.5 – 6.3 | 3.0 – 5.7 | Similar |
| **Materials** | | | |

| COMPARISON | SUBJECT DEVICE | REFERENCE DEVICE | COMPARISON |
|---|---|---|---|
| **Abutment** | Ti-6Al-4V alloy (ASTM F136) | Titanium alloy, ASTM F136 | Same |
| **Screw** | Ti-6Al-4V alloy (ASTM F136) | Titanium alloy, ASTM F136 | Same |
| **Sterilization** | | | |
| **Sterilization status and type** | Non-sterile<br>End user steam sterilization | Non-sterile<br>End user steam sterilization | Same |
| **Multi-unit Abutments** | | | |
| **Abutment/Implant Platform Diameter (mm)** | 3.5 – 6.3 | 3.0 – 7.0 | Similar |
| **Prosthetic Platform Diameter (mm)** | 4.8 | 4.8 | Same |
| **Abutment Angle** | Straight (0°) | 0°, 17°, 30° | Similar |
| **Intended Restoration Type** | Multi-unit | Multi-unit | Same |
| **Gingival Height** | 1.4 – 4.15 | 0.9 – 5.0 | Similar |
| **Surface Coating** | Uncoated | TiN | Different |

*Table 4. Subject and Reference devices technological characteristic comparison (Temporary)*

| COMPARISON | SUBJECT DEVICE | REFERENCE DEVICE | COMPARISON |
|---|---|---|---|
| **General Design Features** | | | |
| **Device** | Bonafix Implant Abutment<br>Zentek Medical LLC | IPD Dental Implant Abutments<br>(Implant Protesis Dental 2004, SL)<br>(K240570) | |
| **Abutment Designs** | Temporary<br>Multi-Unit Straight<br>Titanium Base | Healing<br>Temporary<br>Cementing<br>Ti-Base | Similar |
| **Prosthesis Attachment** | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Same |
| **Restoration Type** | Single-unit (Crowns)<br>Multiple-unit (bridges) | Single-unit (Crowns)<br>Multiple-unit (bridges) | Same |
| **Abutment/Implant Platform Diameter (mm)** | 3.5 – 6.3 | 3.0 – 5.7 | Similar |
| **Materials** | | | |
| **Abutment** | Ti-6Al-4V alloy (ASTM F136) | Titanium alloy, ASTM F136 | Same |
| **Screw** | Ti-6Al-4V alloy (ASTM F136) | Titanium alloy, ASTM F136 | Same |
| **Sterilization** | | | |

| COMPARISON | SUBJECT DEVICE | REFERENCE DEVICE | COMPARISON |
|---|---|---|---|
| **Sterilization status and type** | Non-sterile<br>End user steam sterilization | Non-sterile<br>End user steam sterilization | Same |
| **Temporary Abutments** | | | |
| **Abutment/Implant Platform Diameter (mm)** | 3.5 – 6.3 | 3.0 – 5.7 | Similar |
| **Abutment Angle** | Straight (0°) | Straight (0°) | Similar |
| **Intended Restoration Type** | Single-unit / Multi-unit | Single-unit / Multi-unit | Same |
| **Surface Coating** | Uncoated | Anodized | Different |

The data included in this submission demonstrate substantial equivalence to the predicate and references devices. It is considered that the subject device is substantially equivalent based on the following aspects:

- Has the same intended use;
- Uses the same operating principle;
- Incorporates similar design and same device categories;
- Incorporates the same materials;
- It is sterilized using the same processes.

Materials and technological characteristics of the subject device are identical to previously cleared Bonafix Implant Abutments (primary predicate device). Subject device categories are very similar in design, with differences on the proposed compatibilized OEM dental implant systems.

The other reference devices K120243 and K193352 serve as references for the cement and software used in the design of the Bonafix TiBase abutment restoration.

X) Summary of Non-Clinical Testing

The proposed devices have been subject to bench testing to determine fulfilment of design and performance requirements. Bench testing followed the recommendations provided in FDA Guidance Document – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Specifically, non-clinical performance testing on the Bonafix Implant Abutments include:

- Sterilization validation to achieve a SAL of 1 x 10-6 according to ISO 17665-1 to ensure sterilization of the final finished device.
- Cytotoxicity testing according to ISO 10993-5 to demonstrate that all patient-contacting surfaces are non-cytotoxic.
- Reverse engineering and dimensional analysis of original manufacturer's components (implants, abutments and screws) to confirm compatibility.

- Non-clinical worst-case MRI review was performed to evaluate Bonafix Implant Abutments in the MRI environment using scientific rationale and published literature (i.e., *Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795)*, for the entire system (including all variations of compatible implant bodies, dental abutments, and fixation screws) and material composition. The rationale addressed parameters per the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*", including magnetically induced displacement force and torque.

Non-clinical performance testing leveraged from K221673, previously cleared, showed that Bonafix Implant Abutments met the applicable specifications and requirements.
No clinical testing was performed, the determination of substantial equivalence is supported by nonclinical testing.

XI) Summary of Clinical Testing

No clinical testing was performed in support of this submission.

XII) Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K221673 and Reference Devices K242819 and K240570.