October 3, 2018

Neobiotech Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K181138
Trade/Device Name: IS-III active System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 30, 2018
Received: September 6, 2018

Dear April Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
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)*

K181138

Device Name
IS-III active System

Indications for Use *(Describe)*

The IS-III active System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IS-III active System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.

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

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

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

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**510(k) Summary**

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**Device Information**

- Trade Name: IS-III active System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 10/03/2018

**Predicate Devices:**
The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K113554, CMI Implant IS System manufactured by Neobiotech Co., Ltd.

Reference Devices

- K120503, CMI Implant IS II active manufactured by Neobiotech Co., Ltd
- K160828, Dentum Implantium® / SuperLine® Prosthetics manufactured by Dentium Co., Ltd.
- K173938, IS-III HActive Fixture manufactured by Neobiotech Co., Ltd.
- K070228, Implantium Prosthetics by Dentium Co.,Ltd.

**Indications for Use:**
The IS-III active System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IS-III active System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.

**Device Description**

IS-III active System is composed of IS-III active fixtures and Abutments. IS-III active Fixture is a thread type implant made of TI CP4 according to ASTM F67 which will be placed in the alveolar bone to replace the function of the missing tooth. This device has connection between the upper prosthesis and the internal hex.
Fixture's surface is treated with SLA (Sandblasted with Large-grit and Acid-etching). It is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone).

There are 4 types of fixtures in this system and the dimensions are as following:

| Fixture Type | Diameter (mm) | Length (mm) |
|---|---|---|
|  | Ø 3.5 | 8.5/10.0/11.5/13.0/15.0 |
| | Ø 4.0/4.5/5.0 | 7.3/8.5/10.0/11.5/13.0/15.0 |
|  | Ø 3.5 | 8.5/10.0/11.5/13.0/15.0 |
| | Ø 4.0/4.5/5.0/5.5 | 7.3/8.5/10.0/11.5/13.0/15.0 |
| | Ø 6.0/7.0 | 7.3/8.5/10.0/11.5/13.0 |
|  | Ø 3.5 | 8.5/10.0/11.5/13.0/15.0 |
| | Ø 4.0/4.5/5.0/5.5 | 7.3/8.5/10.0/11.5/13.0/15.0 |
| | Ø 6.0 | 7.3/8.5/10.0/11.5/13.0 |
| | Ø 7.0 | 7.3/8.5/10.0/11.5 |
|  | Ø 3.5 | 8.5/10.0/11.5/13.0/15.0 |
| | Ø 4.0/4.5/5.0/5.5 | 7.3/8.5/10.0/11.5/13.0/15.0 |
| | Ø 6.0/7.0 | 7.3/8.5/10.0/11.5/13.0 |

Tolerance of dimension shall be within ± 1% range.

IS-III active System Abutments are composed of IS Cover Screw, IS Healing Abutment, IS Encoded Healing Abutment, IS Solid Abutment, Protective Cap, IS Cemented Abutment, IS Shapable Abutment, IS Angled Abutment, IS Gold UCLA Abutment, IS Temporary Abutment, IS Ball Abutment, IS Ball Abutment Component (Housing, Retainer, O-ring) and IS Abutment Screw.
The dimensions of abutments are as following:

| Name | | Diameter (mm) | Length of Cuff (mm) |
|---|---|---|---|
| IS Cover Screw | | Ø 3.45 | 5.85/6.85/7.45 |
| | | Ø 3.6 | 6.4/7.4/8.0 |
| IS Healing Abutment | | Ø 4.8/5.5/6.0/6.8 | Cuff: 2.8/3.8/4.8/5.8/6.8/7.8 |
| | | Ø 4.0/4.5 | Cuff: 2.3/3.3/4.3/5.3/6.3 |
| | | Ø 8.0/9.0 | Cuff: 2.8/3.8/4.8 |
| IS Encoded Healing | Body | Ø 4.0/4.6 | Cuff: 3.3/4.3/5.3/6.3/7.3 |
| | | Ø 5.3/5.8/6.6/8.0/9.0 | Cuff: 2.3/3.3/4.3/5.3 |
| | Screw | Ø 2.3 | 8.4/9.4/10.4/11.4/12.4/13.4 |
| IS Solid Abutment | | Ø 4.5/5.2/5.7/6.5 | 4.0/4.5/5.5/7.0 |
| Protective cap | | Ø 5.0/5.7/6.2 | 5.5/6.3/7.3/8.8 |
| | | Ø 7.1 | 5.5/6.3/7.75/9.25 |

| | | | |
|---|---|---|---|
| IS Cemented Abutment | | Ø 4.5/5.2/5.7 | 4.0/4.5/5.5/7.0/8.0 |
| | | *Ø6.5 | 4.0/4.5/5.5/7.0/8.0 |
| | | **Ø4.5 | 5.5/7.0 |
| | | **Ø5.2/5.7 | 4.0/4.5/5.5/7.0 |
| IS Shapable Abutment | | Ø 4.5/5.2/5.7 | 8.1/11.1 |
| | | Ø 6.5 | 8.1 |
| IS Angled Abutment | | Ø 4.5/5.2/5.7 | 7.0 |
| IS Ball Abutment | | Ø 3.5 | 11.1/12.1/13.1/14.1 |
| IS Ball Abutment _component | Housing | Ø 5.0 | 4.0 |
| | Retainer | Ø 5.0 | 2.0 |
| | O-ring | Ø 4.6 | - |
| | | Ø 4.7 | - |
| IS Gold UCLA Abutment | | Ø 4.5 | 10.0 |
| IS Temporary Abutment | | Ø 4.5 | 6.0/8.0/11.5 |
| Abutment Screw | | Ø 2.3 | 8.8/8.3 |

* Not all Ø6.5 diameter abutments are available in 8.0 length.

** Theses are a separate type of IS Cemented Abutment.

The features of each abutment are as following:

| Name | Uses | Surface Treatment | Connection |
|---|---|---|---|
| IS Cover Screw | It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture | Anodizing (yellow), Non-Anodizing | Screw Retained |
| IS Healing Abutment | Used to formation appropriate gingival shape during the soft tissue healing period combined with implant | N/A | Screw Retained |
| IS Encoded Healing Abutment | | N/A | Internal Hex |
| IS Solid Abutment | The Abutment is connected with fixture and it supports prosthesis which restores tooth function. | TiN-Coating | Screw Retained |
| IS Cemented Abutment | | | Internal Hex, Non-Hex, SCRP |
| IS Shapable Abutment | | | |
| IS Angled Abutment | | | Internal Hex, Non-Hex |
| IS Ball Abutment | | N/A | Screw Retained |
| IS Gold UCLA Abutment | | N/A | Internal Hex, Non-Hex, SCRP |
| IS Temporary Abutment | | N/A | |
| Protective Cap | Used to protect Solid Abutments in the oral cavity. | N/A | - |
| IS Abutment Screw | It is used to fix Abutment at the top of fixture | N/A | Screw Retained |

Tolerance of dimension for Abutments shall be within ± 1% range.

The purpose of Anodizing for Cover Screw is to distinguish the sizes with the naked eyes for convenience. The surface of IS Solid, cemented, Shapable, Angled Abutments was treated with TiN-Coated.

IS-III active Fixture, IS cover screw, and healing Abutments are provided sterilized. And other Abutments are provided non- sterilized.
IS-III active Fixture is enclosed with Cover Screw in a packing. Other Abutments are enclosed with Abutment Screw in a packing. The Solid Abutment is enclosed with Protective cap.
All of above products including enclosed product are packed separately for convenience.

**Materials:**

- The Fixtures are made of TI CP4 of ASTM F67.
- The Abutments (IS Cover Screw, IS Healing Abutment, IS Encoded Abutment, IS Solid Abutment, IS Cemented Abutment, IS Shapable Abutment, IS Angled Abutment, IS Temporary Abutment, IS Abutment Screw) are fabricated from Ti-6Al-4V ELI of ASTM F136.
- The IS Gold UCLA Abutment is fabricated from Gold Alloy and Polyoxymethylene (POM) of ASTM F1855.
- The Protective Cap is fabricated from Polyoxymethylene (POM) of ASTM F1855.
- The IS Ball Abutment attachments are fabricated from Ti-6Al-4V ELI of ASTM F136(Housing, Retainer) and Silicon(O-ring).

**Summaries of Technological Characteristics:**

**1) IS-III active Fixture**

| | Subject Device | Primary Predicate | Reference Device |
|---|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. | Neobiotech Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System | CMI Implant IS II active |
| 510(k) Number | K181138 | K113554 | K120503 |
| Device Classification Name | Implant, Endosseous, Root-Form | Implant, Endosseous, Root-Form | Implant, Endosseous, Root-Form |
| Product Code | DZE | DZE | DZE |
| Regulation Number | 872.3640 | 872.3640 | 872.3640 |
| Indications for Use | The IS-III active System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IS-III active System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. | The CMI Implant IS System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IS System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with | The CMI Implant IS II active is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. |

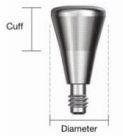
| | | | |
|---|---|---|---|
| | Also, implants with diameters larger than 5mm are indicated for molar regions. | diameters larger than 5mm are indicated for molar regions. | |
| Material | TI CP4 of ASTM F67 | TI CP4 of ASTM F67 | TI CP4 of ASTM F67 |
| Design |  |  |  |
| Anti-Rotational Feature | Internal Hex | Internal Hex | Internal Hex |
| Diameters(Ø) | 3.5/4.0/4.5/5.0/5.5/6.0/7.0 | 3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0 | 3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0 |
| Lengths(mm) | 7.3/8.5/l0.0/l1.5/13.0/15.0 | 7.3/8.5/l0.0/l1.5/13.0/15.0 | 7.3/8.5/10.0/11.5/13.0/15.0 |
| Surface Treatment | SLA | RBM | SLA |
| Sterilization | Gamma Sterilization | Gamma Sterilization | Gamma Sterilization |
| Principle of Operation | This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture. | This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture | This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture. |
| Similarities | The IS-III active Fixture has same device characteristics with the Primary predicate devices, CMI Implant IS System (K113554) such as diameters, Length, intended use, material, functions, general shape (Design), structure and applied production method are similar. | | |
| Differences | The differences between the subject device and the primary predicate device is surface treatments and product design. The surface treatment method of the predicate fixture is RBM (Resorbable Blasting Media) and the surface treatment method of the subject device is SLA (Sandblasted with Large-grit and Acid-etching). To support this discrepancy, K120503 was added as a reference device which was treated with SLA method. | | |

**2) IS Cover Screw**

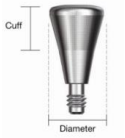
| | Subject Device | Primary Predicate | Reference Device |
|---|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. | Neobiotech Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System | IS-III HActive Fixture |
| 510(k) Number | K181138 | K113554 | K173938 |
| Material | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 |
| Design |  |  |  |
| Diameters(Ø) | 3.45/3.6 | 3.19/3.35 | 3.45/3.6 |
| Lengths(mm) | 5.85/6.85/7.45/ 6.4/7.4/8.0/ | 5.45/5.85 | 5.85/6.85/7.45/ 6.4/7.4/8.0/ |
| Surface Treatment | Anodizing/ Non-Anodizing, | N/A | Anodized/Non-Anodized |

| Sterilization | Gamma Sterilization | Gamma Sterilization | Gamma Sterilization |
|---|---|---|---|
| Principle of Operation | It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed. | It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed. | It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed |
| Similarities | The subject device has same intended use, material, functions, principle of operation, shelf life and similar design and dimensions. | | |
| Differences | There are slightly different designs and dimensions. Also, the subject device includes anodized cover screw. To support the dimension, K173983 was referenced. This change doesn't affect product's fundamental function, safety and effectiveness. | | |

**3) IS Healing Abutment**

| | Subject Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. | Dentium Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System | Implantium Prosthetics |
| 510(k) Number | K181138 | K113554 | K070228 |
| Material | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 | Titanium Grade 4 of ASTM F67 |
| Design |  |  |  |
| Diameters (Ø) | 4.0/4.5/4.8/5.5/6.0/6.8/8.0/9.0 | 4.8/5.5/6.0/6.8 | 4.0/4.5/5.5/6.5/7.5/8.5/9.5 |
| Cuff(mm) | 2.3/2.8/3.3/3.8/4.3/4.8/5.3/5.8/ 6.3/6.8/7.8/ | 2.0/3.0/4.0/5.0/6.0/7.0/8.0 | 2.0/3.5/5.0/7.0 |
| Surface Treatment | N/A | N/A | N/A |
| Sterilization | Gamma Sterilization | Gamma Sterilization | Gamma Sterilization |
| Principle of Operation | This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up. | This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up. | Implantium Prosthetic is intended for use as an aid in prosthetic rehabilitation. |
| Similarities | The subject device has same intended use, functions, material, surface treatment, principle of operation, shelf life and similar design and heights as the primary predicate. | | |
| Differences | There are slightly different diameters between the subject and primary predicate device. K070228 was added to support the large diameters of the subject healing abutments such as 8.0 and 9.0mm. | | |

**4) IS Encoded Healing Abutment**

| | Subject Device | Primary Predicate Device | Reference Device | Reference Device |
|---|---|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. | Biomet 3i. | Dentium Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System | Implantium Prosthetics | |
| 510(k) Number | K181138 | K113554 | K070228 | |
| Material | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 | Titanium Grade 4 of ASTM F67 | |
| Design |  |  |  | |
| Diameters (Ø) | Body:4.0/4.6/5.3/5.8/6.6/8.0/9.0 | 4.8/5.5/6.0/6.8 | 4.0/4.5/5.5/6.5/7.5/8.5/9.5 | |
| Lengths (mm) | Body Cuff: 2.3/3.3/4.3/5.3/6.3/7.3 | 2.0/3.0/4.0/5.0/6.0/7.0/8.0 | 2.0/3.5/5.0/7.0 | |
| Surface Treatment | N/A | N/A | N/A | |
| Sterilization | Gamma Sterilization | Gamma Sterilization | Gamma Sterilization | |
| Principle of Operation | This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up. It is two-piece type which is consist with Healing Abutment and Abutment screw. The occlusal surface of the device includes machined markings that provide information about the mating implant's position and orientation. | This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up. | Implantium Prosthetic is intended for use as an aid in prosthetic rehabilitation. | |
| Similarities | The subject device has same intended use, material, function, surface treatment, principle of operation and similar dimensions as the primary predicate. | | | |
| Differences | There are slightly different dimensions. To support diameters, K070228 was added and to support heights, K070228 were added. | | | |

**5) IS Solid Abutment**

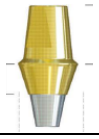
| | Subject Device | Primary Predicate Device |
|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System |
| 510(k) Number | K181138 | K113554 |
| Material | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 |

| | | |
|---|---|---|
| Design |  |  |
| Diameters (Ø) | 4.5/5.2/5.7/6.5 | 4.5/5.2/5.7/6.5 |
| Lengths(mm) | 4.0/4.5/5.5/7.0 | 4.5/5.5/6.0/7.0/8.0 |
| Surface Treatment | TiN-Coating | TiN-Coating |
| Principle of Operation | It is one body cement retained restoration, connected with fixture and cemented crown on the Abutment. | It is one body cement retained restoration, connected with fixture and cemented crown on the Abutment. |
| Similarities | The subject device has same intended use, material, function, surface treatment, principle of operation and similar design and dimensions. | |
| Differences | The dimensions are slightly different but it doesn't affect device's fundamental functions. | |

**6) Protective Cap**

| | Subject Device | Predicate Device |
|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System |
| 510(k) Number | K181138 | K113554 |
| Material | Polyoxymethylene (POM) of ASTM F1855 | Polyoxymethylene (POM) of ASTM F1855 |
| Design |  |  |
| Diameters (Ø) | 5.0/5.7/6.2/7.1 | 4.5/5.2/5.7/6.5 |
| Lengths(mm) | 5.5/6.3/7.3/8.8/7.75/9.25 | 4.5/5.5/6.0/7.0/8.0 |
| Surface Treatment | N/A | N/A |
| Principle of Operation | Used to protect Solid Abutments in the oral cavity. | Used to protect Solid Abutments in the oral cavity |
| Similarities | The subject device has same intended use, material, function, principle of operation and similar design and dimensions. | |
| Differences | The dimensions are slightly different but it doesn't affect device's fundamental functions. | |

**7) IS Cemented Abutment / IS Shapable Abutment/ IS Angled Abutment**

| | Subject Device | | | Primary Predicate Device | | | Reference Device |
|---|---|---|---|---|---|---|---|
| Company | Neobiotech Co., Ltd | | | Neobiotech Co., Ltd. | | | Dentium Co., Ltd. |
| Device Name | IS-III active System | | | CMI Implant IS System | | | Dentum Implantium® / SuperLine® Prosthetics |
| 510(k) Number | K181138 | | | K113554 | | | K160828 |
| Material | Ti-6Al-4V ELI of ASTM F136 | | | Ti-6Al-4V ELI of ASTM F136 | | | Pure Titanium Grade4 |
| **IS Cemented Abutment** | | | | | | | |
| Design |  |  |  |  |  |  | - |
| | Hex | Non-Hex | SCRP | Hex | Non-Hex | SCRP | - |
| Diameters (Ø) | 4.5/5.2/5.7/6.5 | | | 4.5/5.2/5.7/6.5 | | | - |
| Lengths(mm) | 4.0/4.5/5.5/7.0/8.0 | | | 4.5/5.5/6.0/7.0/8.0 | | | - |
| **IS Shapable Abutment** | | | | | | | **Dual Milling Abutment** |
| Design |  |  |  |  |  |  |  |
| | Hex | Non-Hex | SCRP | Hex | Non-Hex | SCRP | Hex and Non-Hex |
| Hand Milling Only | Yes | | | Yes | | | Yes |
| Diameters(Ø) | 4.5/5.2/5.7/6.5 | | | 4.5/5.2/5.7/6.5 | | | 4.0~6.5 |
| Lengths(mm) | 8.1/11.1 | | | 4.5/5.5/6.0/7.0/8.0 | | | 14.7 |
| **IS Angled Abutment** | | | | | | | |
| Design |  |  |  |  | | | - |
| | Hex | Non-Hex | Hex | Non-Hex | | | - |
| Diameters (Ø) | 4.5/5.2/5.7 | | 4.5/5.2/5.7/6.5 | | | | - |
| Lengths(mm) | 7.0 | | 7.0/8.0 | | | | - |
| Angle (°) | 15/25 | | 15/25 | | | | - |
| Surface Treatment | TiN-Coating | | TiN-Coating | | | | Non-coated |
| Principle of Operation | It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations. | | It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations. | | | | It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations. |
| Similarities | The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and dimensions as the primary predicate. | | | | | | |
| Differences | 11mm of the length of IS Cemented Abutment was added compared to the primary predicate. To support the 11mm length, K160828 was added. This addition doesn't affect device's fundamental functions, safety and effectiveness. | | | | | | |

**8) IS Ball Abutment**

| | Subject Device | Primary Predicate |
|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System |
| 510(k) Number | K181138 | K113554 |
| Material | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 |
| Design |  |  |
| Diameters (Ø) | Ball Abutment: 3.5<br>Housing:5.0 /Retainer:5.0 /O-Ring:4.5/4.7 | Ball Abutment: 3.5<br>Housing:5.0 /Retainer:5.0 /O-Ring:4.6/4.7 |
| Length(mm) | Ball Abutment:11.1/12.1/13.1/14.1<br>Housing Length:4.0 /Retainer Length:2.0 | Ball Abutment: 11.1/12.1/13.1/14.1<br>Housing Length:4.0 /Retainer Length:2.0 |
| Surface Treatment | N/A | N/A |
| Principle of Operation | Used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored. | Used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored. |
| Similarities | The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and dimensions. | |
| Differences | The diameter of the O-ring is slightly different but it is in the range of the predicate device. | |

**9) IS Gold UCLA Abutment**

| | Subject Device | | | Primary Predicate | | |
|---|---|---|---|---|---|---|
| Company | Neobiotech Co., Ltd | | | Neobiotech Co., Ltd. | | |
| Device Name | IS-III active System | | | CMI Implant IS System | | |
| 510(k) Number | K181138 | | | K113554 | | |
| Material | Gold Alloy/<br>Polyoxymethylene(POM) of ASTM F1855 | | | Gold Alloy/<br>Polyoxymethylene(POM) of ASTM F1855 | | |
| Design |  |  |  |  | - | - |
| | Hex | Non-Hex | SCRP | Hex | Non-Hex | SCRP |
| Diameters (Ø) | 4.5 | | | 4.5/5.5/6.5 | | |
| Length(mm) | 10.0 | | | 10.0 | | |
| Surface Treatment | N/A | | | N/A | | |
| Principle of Operation | It is used when there are restrictions on the prosthesis production because of path, aesthetics, and space of fixture.<br>Production the prosthesis by casting with dental alloy after wax up with desired shape | | | It is used when there are restrictions on the prosthesis production because of path, aesthetics, and space of fixture.<br>Production the prosthesis by casting with dental alloy after wax up with desired shape. | | |
| Similarities | The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and dimensions. | | | | | |
| Differences | There is no difference between the subject and primary predicate. | | | | | |

**10) IS Temporary Abutment**

| | Subject Device | | | Primary Predicate | | | Reference Device |
|---|---|---|---|---|---|---|---|
| Company | Neobiotech Co., Ltd | | | Neobiotech Co., Ltd. | | | Dentium Co., Ltd. |
| Device Name | IS-III active System | | | CMI Implant IS System | | | Dentum Implantium® / SuperLine® Prosthetics |
| 510(k) Number | K181138 | | | K113554 | | | K160828 |
| Material | Ti-6Al-4V ELI of ASTM F136 | | | Ti-6Al-4V ELI of ASTM F136 | | | Pure Titanium Grade4 |
| Design |  |  |  | - |  | - |  |
| | Hex | Non- | SCRP | Hex | Non- | SCRP | Hex/Non-Hex |
| Diameters (Ø) | 4.5 | | | 4.5/5.2/5.7/6.5 | | | 4.5 |
| Length(mm) | 6.0/8.0/11.5 | | | 6.0/8.0 | | | 13.7 |
| Surface Treatment | N/A | | | N/A | | | N/A |
| Principle of Operation | It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made. | | | It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made. | | | It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made |
| Similarities | The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and diameters. | | | | | | |
| Differences | Lengths of the device are longer than the primary predicates. To support this difference, K160828 was added. These differences don't affect device's fundamental functions, safety and effectiveness. | | | | | | |

**11) IS Abutment Screw**

| | Subject Device | Primary Predicate |
|---|---|---|
| Company | Neobiotech Co., Ltd | Neobiotech Co., Ltd. |
| Device Name | IS-III active System | CMI Implant IS System |
| 510(k) Number | K181138 | K113554 |
| Material | Ti-6Al-4V ELI of ASTM F136 | Ti-6Al-4V ELI of ASTM F136 |
| Design |  |  |
| Diameters (Ø) | 2.3 | 2.3 |
| Length (mm) | 8.8/8.3 | 7.55/9.55 |
| Surface Treatment | N/A | N/A |
| Principle of Operation | This product is a screw for connected with Abutment and fixture. | This product is a screw for connected with Abutment and fixture. |
| Similarities | The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and diameters. | |
| Differences | The design of the devices is slightly different but it doesn't affect device's fundamental functions, safety and effectiveness. | |

Similarities:
The IS-III active Fixture has same device characteristics with the Primary predicate devices, CMI Implant IS System (K113554) such as diameters, Length, intended use, general shape (Design), structure, fundamental technologies and applied production method are similar.
The IS-III active Abutments are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics as predicate devices. Testing including performance and fatigue test has been finished to ensure the devices comply with the applicable International and US FDA Guidance.

Differences:
The differences between the subject device and the primary predicate device are surface treatment. The surface treatment method of the subject fixture is SLA (Sandblasted with Large-grit and Acid-etched) and the surface treatment method of the primary Predicate device is RBM (Resorbable Blasting Media). To support this discrepancy, K120503 was selected as Reference Device for the fixtures and biocompatibility testing was performed on the subject device. The dimensions of various Abutments are slightly different from the predicate devices. However, the dimensions of the subject device are in the range of the dimensions of the primary and reference devices. Therefore, this dimensional difference doesn't affect device safety and effectiveness.

**Non-clinical testing data:**
The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 on fixtures
- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario
- Bacterial Endotoxin Test Report according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1
- Gamma sterilization validation Test Report according to ISO 11137-1, ISO 11137-2 and ISO 11137-3
- Shelf Life Test according to ASTM F1980, ASTM D882, ASTM F1140, ASTM F1929, and ASTM F2096

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.
Biocompatibility Test was conducted on the subject fixtures and it demonstrates that the subject device is biocompatible and substantial equivalence with the predicate device.
Biocompatibility test performed on our previously cleared predicate K113554 can be leveraged for the subject abutments because they are made of same materials and have same manufacturing process.
Fatigue testing for IS-III active fixture and angled Abutment was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" and ISO 14801:2016 Dentistry - Fatigue test for endosseous dental implants under the worst-case scenario. The results ensure that the subject device is substantially equivalent.
Sterilization Validation and Shelf Life testing for fixtures and healing abutments was conducted on the predicate devices. Since the materials, manufacturing process, sterilization method, packaging materials

and methods are identical between the subject and predicate devices, the test reports can be leveraged for the subject device.
The shelf life for fixtures and healing abutments are 5 years.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

**Conclusion**

IS-III active System constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, IS-III active System and its predicates are substantially equivalent.