June 19, 2020

F&B Technology Co., Ltd.
℅ Yang Ho Dong
Manager
Onbix Corporation
#821 Samil Plaza, 14, Dogok-ro 1-gil, Gangnam-gu
Seoul 46977
REPUBLIC OF KOREA

Re: K190637
Trade/Device Name: Fit & Brilliant Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 8, 2020
Received: June 18, 2020

Dear Ho Dong Yang:

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K190637

Device Name
Fit & Brilliant Dental Implant System

Indications for Use *(Describe)*
The Fit & Brilliant Dental Implant 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. The Fit &Brilliant Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

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.***

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# 510(k) SUMMARY
# K190637

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.


**Submitter Information:** **F&B Technology Co., Ltd.**
17-230, #37, Kwaegam-ro, Sasang-ku, (Kwaebop, Ind. Supplies Market) Busan, Korea
Tel. +82-(0)51-319-3214, 1230, 1240

**Contact Person:** Ho Dong, Yang
Onbix Corporation
#821 Samil Plaza, 14 Dogokro 1-gil
Gangnam-gu, Seoul, Korea (06253)
Tel: *82-2-566-3360 / Fax: *82-2-6280-3360
Email: onbix@naver.com


**Date Summary Prepared:** June 19, 2020

**Device Information:**

| | |
|---|---|
| Trade Name(s): | **Fit & Brilliant Dental Implant System** |
| Classification Name: | Endosseous Dental Implant |
| Panel: | dental |
| Product Code & Regulation: | DZE / NHA |

**Primary Predicate Device Information:**
K132956 / U fit Dental Implant System

**Device Description:**
This medical product is for dental implant that is a surgical component that interfaces with the bone of the jaw to support a dental prosthesis such as a crown, bridge, denture. It is inserted in the jaw to support and maintain the prosthodontic restorative tooth or denture when the tooth is partially or totally lost. It is made of titanium material (ASTM F136 Ti 6Al-4V ELI) that is a widely used in the market. The surface of the produce is treated with powder for CaP, and it is designed to connect with the superstructure that abutment by internal fastening method. This is disposable product sterilized by gamma sterilization method and it prevents re-sterilization or reuse.

**Indications for Use:**
The Fit & Brilliant Dental Implant 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. The Fit &Brilliant Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

**Comparison to Predicate Device(s):**
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

**Summary of the technological characteristics compared to the predicate device**
new device is substantially equivalent to the predicate device in its technological characteristics stated in below comparison table

# Comparative table

**1) Fixture**

| | **Subject device** | **Predicate device** |
|---|---|---|
| **Device name** | Fit & Brilliant Dental Implant System | U fit Dental Implant System |
| **510(k) number** | K190637 | K132956 |
| **Manufacturer** | F&B Technology Co., Ltd | T Strong, Inc. |
| **Intended use** | Identical to the predicate | The U fit Dental Implant 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. The Fit & Brilliant Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading. |
| **The principle** | Identical to the predicate | This medical product is a fixture for dental implant that is a surgical component that interfaces with the bone of the jaw to support a dental prosthesis such as a crown, bridge, denture. It is inserted in the jaw to support and maintain the prosthodontic restorative tooth or denture when the tooth is partially or totally lost. It is made of titanium material (ASTM F136 Ti 6Al-4V ELI) that is a widely used in the market. The surface of the produce is treated with powder for CaP series, and it is designed to connect with the superstructure that abutment by internal fastening method. This is disposable |

| | | |
|---|---|---|
| | | product sterilized by gamma sterilization method and it prevents re-sterilization or reuse. |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI ASTM F136 |
| **Design** |  |  |
| **Fixture Type** | Submerged Type | Submerged Type |
| **Implant diameter** | Φ3.9, Φ4.1, Φ4.4, Φ4.8, Φ5.3, Φ5.8, Φ6.3, Φ6.8 [mm] | Φ3.8, Φ3.9, Φ4.0, Φ4.1, Φ4.5, Φ5.0, Φ5.5, Φ6.0, Φ6.5, Φ7.0 [mm] |
| **Implant length** | 7, 8.5, 10, 11.5, 13, 14.5 [mm] | 7, 8.5, 10, 11.5, 13, 14.5 [mm] |
| **Connection** | 2.5 Hex. Indentation and 11[°] Morse taper | 2.5 Hex. Indentation and 11[°] Morse taper |
| **Components** | Various abutments and accessories | Various abutments and accessories |
| **Surface treatment** | RBM | RBM |
| **Gamma sterilized** | Yes | Yes |
| **Product Code** | DZE | DZE |

| **2) Abutment** | | |
|---|---|---|
| | **Subject device** | **Predicate device** |
| **Device name** | Fit & Brilliant Dental Implant System | U fit Dental Implant System |
| **510(k) number** | NA | K132956 |
| **Manufacturer** | F&B Technology Co., Ltd | T Strong, Inc. |
| **Product description** | Identical to the predicate | This abutment product is used to attach a crown, bridge, or removable |

| | | |
|---|---|---|
| | | denture to the dental implant fixture. It is made of titanium material (ASTM F136 Ti 6Al-4V ELI) that is a widely used in the market. It is designed to connect with the dental fixture by internal fastening method. This is a disposable product requires user sterilization with autoclave and it prevents re-sterilization or reuse. |
| **Product Code** | NHA | NHA |
| **Cover Screw** | | |
| **Design** |  |  |
| **Intended use** | To provide sealing effect for fixture | To provide sealing effect for fixture |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI Gr.23 |
| **Sterilization** | Steam Sterilization by user | Steam Sterilization by user |
| **Abutment Screw** | | |
| **Design** |  |  |
| **Intended use** | To connect abutment to fixture | To connect abutment to fixture |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI ASTM F136 |
| **Sterilization** | Steam Sterilization by user | Steam Sterilization by user |
| **Healing Abutment** | | |

| | | |
|---|---|---|
| **Design** |  |  |
| **Intended use** | To help the soft tissue of gum naturally formed | To help the soft tissue of gum naturally formed |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI Gr.23 |
| **Sterilization** | Steam Sterilization by user | Steam Sterilization by user |
| **Solid Abutment** | | |
| **Design** |  |  |
| **Intended use** | Cement retained restoration | Cement retained restoration |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI Gr.23 |
| **Sterilization** | Steam Sterilization by user | Steam Sterilization by user |
| **Transfer Abutment** | | |
| **Design** |  |  |
| **Intended use** | Cement retained restoration | Cement retained restoration |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI Gr.23 |
| **Sterilization** | Steam Sterilization by user | Steam Sterilization by user |
| **Angled Abutment** | | |

| | | |
|---|---|---|
| **Design** |  |  |
| **Intended use** | Cement retained restoration (15, 25[°]) | Cement retained restoration (15, 25[°]) |
| **Material** | Ti-6Al-4V ELI ASTM F136 | Ti-6Al-4V ELI ASTM F136 |
| **Sterilization** | Steam Sterilization by user | Steam Sterilization by user |
| | | |
| | | |
| | | |

**Non-Clinical Study performance**

To demonstrate substantial equivalence, the following studies have been performed on the new device (K190637) in accordance with these standards:

ISO 10993-5 cytotoxicity
ISO 10993-10 skin irritation, sensitization
ISO10993-10:skinirritation,sensitization
USP 29 Biological tests <151> pyrogen test
USP<85> BET endotoxin testing
ISO 14801: dynamic fatigue testing
ISO 11737-2: 2009, Sterilization of medical devices
ISO 17665-1, ISO 17665-2, End-User Sterilization
ASTM F88, ASTM F1140, ASTM F1929, ASTM F2096: accelerated aging
Surface Assessment Evaluation

**Conclusion**

New device (K190637) has the same device characteristics as the predicate device, Based on the information provided in this summary we conclude that New device (K190637) is substantially equivalent to the predicate device K132956