DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 10, 2017

Neobiotech Co., Ltd.
% April Lee
Consultant
Withus Group Inc
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K160991
Trade/Device Name: Neo Gbr System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: December 6, 2016
Received: December 12, 2016

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Michael J. Ryan -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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160991

Device Name
Neo GBR System

Indications for Use *(Describe)*
Neo GBR System is intended to fixate and stabilize non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in dental situations that require membrane use or fixation.

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.

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**510(k) Summary**

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**Device Information**

- Trade Name: Neo GBR System
- Common Name: Membrane fixation pin
- Classification Name: Intraosseous Fixation Screw or Wire
- Product Code: DZL
- Panel: Dental
- Regulation Number: 872.4880
- Device Class: Class II
- Date Prepared: 01/10/2017

**General Description**
The Neo GBR System is made of Titanium Alloy. This product is a sterilized single use medical device. This system consists of Tent screw and CTi Cover Screw.
The function of the Tent Screw is temporarily Intraosseous Fixation Screw that places in the maxilla or mandible bone area to be combined with a titanium membrane of K111761 and CTi cover screw. Second surgery for removal is required.
The product diameters are 2.0mm and the lengths are 7.2/8.7/10.2/11.7/13.2/15.2/18.2mm.
The Tent Screw and CTi-Cover screw are always packaged together. But CTi-Cover Screw is packaged separately for the convenience. 4 pcs of Tent Screw can be packaged in a box as a bundle set.

**Indication for Use:**
Neo GBR System is intended to fixate and stabilize non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in dental situations that require membrane use or fixation.

**Materials:**
The devices are fabricated from Ti-6Al-4V ELI of ASTM F136.

**Non-clinical testing data:**
Bench testing was conducted with the predicate device to confirm that the Neo GBR System has the safe and effective physical properties through the visual test, dimension test, compressive loads, pull out, driving torque, and insertion-elimination tests in accordance with ASTM F543-13. The testing results meet the requirements of its pre-defined acceptance criteria and intended uses. Biocompatibility tests such as cytotoxicity, irritation and sensitization tests were performed in accordance with ISO 10993-1. The stability and compatibility tests between the tent screw and CTi-cover screw were performed to evaluate adaptation accuracy.

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

- K143730, GBR system manufactured by Jeil Medical Corporation

**Comparison to Predicate Devices:**

| | Subject Device | Predicate Device |
|---|---|---|
| Company | Neobiotech. Co., Ltd | Jeil Medical Corporation |
| Device Name | Neo GBR System | GBR system |
| 510(k) Number | K160991 | K143730 |
| Device Classification Name | Screw, fixation, intraosseous | Screw, fixation, intraosseous |
| Product Code | DZL | DZL |
| Regulation Number | 872.4880 | 872.4880 |
| Intended Use | Neo GBR System is intended to fixate and stabilize non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in dental situations that require membrane use or fixation. | The GBR System is intended for use in stabilizing and fixating bone grafts, bone filling materials and/or barrier membranes use for guided bone/tissue regeneration in the oral cavity. |
| Material | Ti-6Al-4V ELI of ASTM F136, | Ti-6Al-4V ELI of ASTM F136 |
| Design |  |  |
| Component | Tent screw and CTi cover screw | Bone screw body and Bone screw cap |
| Screw Diameters | Ø2.0 mm | Ø 1.6mm / 1.4mm |
| Screw Lengths | 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2 mm | 3.0, 4.0, 5.0, 6.0, 8.0, 10.0, and 12.0 mm |
| Pitch Size | 0.85 | 0.2 |
| Cover Screw Diameter | 1.55 mm | Ø 1.4mm |

| | | |
|---|---|---|
| Cover Screw Length | 3 mm | 2.4 mm |
| Sterilization | Gamma Sterilization | Non-Sterile |
| Principle of Operation | identical | The function of Bone screw body is temporary dental implant (Screw) that place in maxilla or mandible bone area to be combined with titanium membrane and cover screw or cover cap. It helps to support the membrane. Second surgery for removal is required. |

**Substantial Equivalence Discussion**
The subject device has similar in indications, technology, functions, and materials with the predicate K143730, GBR system by Jeil Medical Corporation.

The differences between the subject device and the predicate device are sterilization and Tent Screw's dimensions and design.
Our product is Gamma sterilized and predicate device is provided non sterile. We performed the sterilization validation testing for the subject device.

The difference of design of the Tent screw is the head part of the screw. The screw part of Tent screw has same function and structure with other predicate GBR screw. However the head part of tent screw has wide structure and have an inner hole connected with Cover screw to hold the titanium membrane for GBR. Therefore, there is no different risk and same stability compared with predicate.
The predicate's diameters are smaller than the subject device. The range of the subject device's lengths is wide and includes predicate's length size.

Based on the comparison of intended use and technical features, the Neo GBR system is substantially equivalent to the predicate device.

**Conclusion**
The Neo GBR System, subject device of this submission, 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. Through non-clinical testing, it has been demonstrated that the different design and indications of the subject device are as safe and as effective as the predicate device. Therefore, Neo GBR System and its predicate are substantially equivalent.