April 30, 2024

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

Re: K232528
Trade/Device Name: Protective Cap
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 7, 2024
Received: April 8, 2024

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 (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.

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232528

Device Name
Protective Cap

Indications for Use *(Describe)*
Protective Cap is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdenture, and can be used for a minimum of 1 day to maximum of 10 days.

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: Protective Cap
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date Prepared: 04/25/2024

Predicate Devices:

Primary Predicate

- K161689, OSSTEM Implant System-Abutment by Osstem Implant Co.,Ltd.

Indications for Use:

Protective Cap is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdenture, and can be used for a minimum of 1 day to maximum of 10 days.

Device Description

The Protective Cap is a dental implant superstructure made of PC(Polycarbonate) according to ASTM F997. It is used temporarily, such as less than 10 days before the final restoration is connected.
The Protective Cap is supplied nonsterile and intended for single use. It is to be sterilized by end users before use.

The dimensions of abutments are as following:

Name	Type	Diameter (Ø)	Length(mm)	Material
Protective Cap	IS	Ø 5.0/5.7/6.2/7.0	5.7/7.2/7.65/8.7	Polycarbonate (ASTM F997)
	IT	Ø 5.45/6.0/7.2/7.7	5.35/5.9/6.85/7.4/ 7.65/8.35/8.9	

The tolerance of dimension shall be within ± 1% range.

The Protective Cap is compatible with Solid Abutment and Cemented Abutment in previously cleared system as below:

Compatible Type	K number	Abutment Name	Diameter (Ø)	Length of Cuff(mm)
Protective Cap for IS Type	K181138	IS Solid Abutment	4.5/5.2/5.7/6.5	4.0/4.5/5.5/7.0
		IS Cemented Abutment	4.5/5.2/5.7/6.5	4.0/4.5/5.5/7.0/8.0
Protective Cap for IT Type	K181137	IT Solid Abutment	3.5/4.3	4.0/5.5/7.0
		IT Excellent Solid Abutment	4.35	5..25/6.75
		IT Cemented Abutment	4.3/4.85/5.5/6.55	5.8/6.0

Summaries of Technological Characteristics:

	Subject Device	**Primary Device**
Company	Neobiotech Co., Ltd	OSSTEM Implant Co., Ltd.
Device Name	Protective Cap	OSSTEM Implant System - Abutment
Abutment Name	Protective Cap	Rigid Protect Cap
510(k) Number	K232528	K161689
Product Code	NHA	NHA
Indications for Use	Protective Cap is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdenture, and can be used for a minimum of 1 day to maximum of 10 days.	OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Material	PC(Polycarbonate)	PC (PolyCarbonate)
Design		
Dimensions	IS: Ø 5.0/5.7/6.2/7.0 X 5.7/7.2/8.7/7.65mm IT: Ø 5.45/7.2/6.0/7.7 X 5.9/7.4/8.9/5.35/6.85/8.35/7.65mm	Ø4.4/5.0/5.5/6.6/7.4 X 5.5/5.7/5.8/5.9/7.0/7.2/7.3/8.5/8.7/8.8 mm
Sterilization	User Steam Sterilization	User Steam Sterilization
Similarities	The subject device has the same intended use, material, functions, principle of operation, sterilization, similar designs, and dimensions.	
Differences	There are slightly different designs and dimensions. These differences do not affect product's fundamental function and the subject device is used temporarily; therefore, it is substantial equivalent.	

Non-clinical testing data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- End User Sterilization Validation Testing according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1
- Biocompatibility Testing according to ISO 10993-1:2018
    - Cytotoxicity tested according to ISO 10993-5: 2009
    - Irritation tested according to ISO 10993-23:2021
    - Sensitization tested according to ISO 10993-10:2021
    - Systemic Toxicity tested according to ISO 10993-11:2017
- Cleaning Process Validation Testing according to ISO 11737-1:2018, ISO/TS 17665-2: 2009

For all subject devices delivered non-sterile to be end-user sterilized, the recommended sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling, issued on March 17, 2015". The worst-case construct was tested.

The Biocompatibility test was conducted on the subject device. We evaluated a biological test in accordance with ISO 10993-1:2018, total of 4 tests were performed: "cytotoxicity", "sensitization", "Oral mucosa irritation", and "systemic toxicity". It demonstrates that the subject device is substantially

equivalent with the predicate device.

Cleaning Process Validation test was evaluated on the worst case sample. Physiochemical test(TOC, pH, electrical conductivity test) and cleaning agent residual test (HPLC), residual on evaporation test, microbial test (Bioburden test) and drying validation tests were conducted. Through these tests, it was confirmed that is effective in terms of cleaning effect.

Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion

Protective Cap 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 device. Therefore, Protective Cap and its predicate are substantially equivalent.