DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 9, 2016

Bomei Co., Ltd
% Shaoyin Peng
Official Correspondent
258 N Bay Dr.
Bullard, Texas 75757

Re: K152297
Trade/Device Name: Obs Anchorage Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: December 29, 2015
Received: January 7, 2016

Dear Shaoyin Peng:

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 801and Part 809); 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 and Part 809), 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,

for Erin I. Keith, M.S.
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)*
K152297

Device Name
OBS Anchorage Screw

Indications for Use *(Describe)*
Temporary anchorage screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth.
It is used temporarily and is removed after orthodontic treatment has been completed.

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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BOMEI CO., LTD.

510(k) summary complying with 21 CFR 807.92.

I. Submitter

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Date prepared: December 29 , 2015

II. Device

Name of the device: OBS Anchorage Screw

Common or Usual Name: OBS Anchorage Screw

Product Type: OBS(BD)

Classification Name: Endosseous dental implant (21 CFR 872.3640)

Regulatory Class: II

Product Code: OAT

III. Predicate Device

K090476(Primary Predicate), Syntec Orthodontic Mini Screws , Syntec Scientific Corporation

K142001(Reference Predicate), Syntec Scientific Corporation , Syntec Wetali Orthodontic Mini Screws

K060126(Reference Predicate), Absoanchor Microimplant , Dentos Inc

K071490(Reference Predicate), Leone SpA , Leone orthodontic mini implant

IV. Intended Use

Temporary anchorage screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth.

It is used temporarily and is removed after orthodontic treatment has been completed.

V. Device Description

OBS Anchorage Screw consists of stainless steel (ISO 5832-1:2007/ASTM F138-13) and titanium alloy (ISO 5832-3:1996/ASTM F136-13) self-tapping screw with various sizes for applications in the orthodontic field. It is intended to serve as a fixed anchorage point for the attachment of orthodontic and pre-prosthetics appliances, in order to facilitate the orthodontic movement of teeth.

OBS Anchorage Screw is available in the following diameter and length.

- Diameter (Ø1.5 mm) x Length (8 / 10 / 12 mm)
- Diameter (Ø2.0 mm) x Length (8 / 10 / 12 / 14 mm)

There are three types of OBS Anchorage Screw.

- Square collar mushroom head none hole
- Square collar mushroom head round hole
- Square collar mushroom head slot hole

OBS Anchorage Screw and associated accessories are supplied non-sterile and should be sterilized before use.

The sterilization recommendations documented in the instructions for use (IFU) are according to “AAMI / ANSI ST79 Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities” have been validated.

Use a pre-vacuum sterilization method minimum 4 minutes at a temperature of 132℃ (270°F). Drying time is 30 minutes.

The devices are used temporarily with the intention to be removed after orthodontic treatment. Screws are intended for single use only.

VI. Table of Safety and Effectiveness Substantial Equivalence Comparison

Device Name	OBS Anchorage Screw	Syntec orthodontic mini screws	Syntec Wetali Orthodontic Mini Screws	Absoanchor Microimplant	Leone orthodontic mini implant
Applicant	BOMEI	Syntec Scientific corporation (Taiwan)	Syntec Scientific corporation (Taiwan)	Dentos Inc (South Korea)	Leone SpA(Italy)
510(K) Number	K152297	K090476	K142001	K060126	K071490
Regulation No.	872.3640	872.3640	872.3640	872.3640	872.3640
Product Code	OAT	OAT	OAT	DZE	OAT
Material	Stainless Steel (ISO 5832-1:2007/ ASTM F138-13) ; Titanium Alloy (ISO 5832-3:1996/ ASTM F136-13)	Stainless Steel (ISO 5832-1:2007/ ASTM F138-13) ; Titanium Alloy (ISO 5832-3:1996/ ASTM F136-13)	Stainless Steel (ISO 5832-1:2007/ ASTM F138-13) ; Titanium Alloy (ISO 5832-3:1996/ ASTM F136-13)	Titanium Alloy (ISO 5832-3:1996/ ASTM F136-13)	Stainless Steel (ISO 5832-1:2007/ ASTM F138-13)
Intended Use	Temporary anchorage screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed.	The screws are intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are intended for single use only.	The screws are indicated for use as a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. They are used temporarily and are removed after orthodontic treatment has been completed. They are intended for single use only.	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.	Provide a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily in the maxillary and mandibular bone and must be removed after orthodontic treatment has been completed.
Supplied Sterile	Non-Sterile ; Steam Sterilize before use	Non-sterile ; Steam sterilize before use.	Non-sterile ; Steam sterilize before use.	Non-Sterile ; Steam Sterilize before use	Non-sterile. It is recommended to sterilize with steam autoclave before use.
Type	Square collar Mushroom head: 1.None hole 2.Round hole 3.Slot hole	The screws are with or without a 0.65mm diameter hold.	The screws are with or without a 0.7mm diameter hold.	1.Small head 2.No head 3.Long head 4.Circle head 5.Fixation head 6.Bracket head 7.Bracket	1.High Head 2.Low head

				head-left handed screw 8.OMAS mushroom	
Length (mm)	8 / 10 / 12 / 14	5-12	6-12	4 -10 & 12	6-12
Diameter (mm)	1.5 / 2	1.3-2	1.4-2	1.2-1.8	1.5-2
Energy Sources	Non-active implantable devices	Non-active implantable devices	Non-active implantable devices	Non-active implantable devices	Non-active implantable devices
Where used	Dental practices	Dental practices	Dental practices	Dental practices	Dental practices
Target population	Professional use only - qualified dentists. Strictly reserved to specialized and trained users.	Professional use only - qualified dentists. Strictly reserved to specialized and trained users.	Professional use only - qualified dentists. Strictly reserved to specialized and trained users.	Professional use only - qualified dentists. Strictly reserved to specialized and trained users.	Professional use only - qualified dentists. Strictly reserved to specialized and trained users.

VII. Comparison Of Technological Characteristics With The Predicate Devices

OBS anchorage screws and predicate devices Syntec Orthodontic Mini Screws , Syntec Wetali Orthodontic Mini Screws , Absoanchor Microimplant , and Leone orthodontic mini implant are based on the following same technological elements.

- Intended use
- Material
- The sterilization method
- Potential adverse effects

The following technological differences exist between the subject and predicate devices.

- The type
- The dimensions (the diameter and the length)

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing has been performed in accordance with ISO 10993-5 , ISO 10993-10 , ISO 10993-11.

- Cytotoxicity: ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity (Biocompatibility)

- Sensitization and Irritation: ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Biocompatibility)
- Systemic toxicity: ISO 10993-11 Biological evaluation of medical devices Part 11: Tests for systemic toxicity. (Biocompatibility)

Sterilization validating testing has been performed in accordance with ISO 11737-1 , ISO 11737-2 and ISO 17665-I , ISO 17665-2 , AAMI / ANSI ST79 for steam sterilization.

- ISO 11737-1 Sterilization Of Medical Devices - Microbiological Methods Part 1: Determination Of The Population Of Microorganisms On Product, 2ed. (Sterility)
- ISO 11737-2 Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process. (Sterility)
- ISO 17665-1 Sterilization Of Health Care Products -- Moist Heat -- Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices. (Sterility)
- ISO 17665-2 Sterilization Of Health Care Products - Moist Heat - Part 2: Guidance On The Application Of ISO 17665-1. (Sterility)
- AAMI / ANSI ST79 Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities.

Mechanical Performance Testing has been performed with the predicate devices Syntec Orthodontic Mini Screws and Absoanchor Microimplant in accordance with ASTM F543 that used in comparative performance testing were performed to demonstrate substantial equivalence.

- ASTM F543 Standard Specification And Test Methods For Metallic Medical Bone Screws.

The results of this testing indicate that OBS Anchorage Screw met acceptance criteria and is substantially equivalent to predicate devices.

IX. Conclusion

In comparison to the legally marketed devices, OBS anchorage screw has the same device characteristics as the predicates devices , intended use, material and the sterilization method.

The differences between the subject device and the predicate devices are the type, the dimensions (the diameter and the length).

However, testing data such as biocompatibility and mechanical performance testing provided in the submission prove that these differences would not raise issues in performance.

Based on the information provided in this premarket notification BOMEI concludes that OBS anchorage screw is substantially equivalent to the predicate device as described herein.

Therefore no clinical testing was conducted.