January 8, 2021

Bomei Co., Ltd.
% Chih-Hao Kao
General Manager
Voler Biotech Consulting Co., Ltd.
No. 3-1, Ln. 58, Hejiang St., Zhongshan Dist.,
Taipei City 10480
TAIWAN

Re: K202278
Trade/Device Name: OBS Anchorage Screw, Biokey Anchorage Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: December 2, 2020
Received: December 11, 2020

Dear Chih-Hao Kao:

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,

Andrew Steen
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202278

Device Name
OBS Anchorage Screw, Biokey 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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K202278

510(k) SUMMARY

OBS Anchorage Screw/Biokey Anchorage Screw

1. Submitter

(a) Contact person

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Date prepared: January 6, 2021

(b) Manufacturer information

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Submitter phone number：	+886-3-355-4989
Submitter fax number：	+886-3-346-0897

2. Device Name and Classification

Product Name:	OBS Anchorage Screw, Biokey Anchorage Screw
Classification Name:	Implant, Endosseous, Orthodontic
Common or Usual Name:	Endosseous dental implant
Classification Panel:	Dental
Regulation Number:	21 CFR 872.3640
Device Class:	Class 2
Product Code:	OAT

3. Predicate Device(s)

K152297 OBS Anchorage Screw

4. Device Description

The OBS/Biokey Anchorage Screw, consisting of stainless steel (SUS-316LVM) and titanium alloy (Ti-6Al-4V ELI), is a 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-prosthetic appliances, in order to facilitate the orthodontic movement of teeth. The OBS/Biokey Anchorage Screw and associated accessories are supplied non-sterile and should be sterilized before use. The devices are used temporarily with the intention to be removed after orthodontic treatment. The average temporary implantation period for the anchorage screw is six months. Screws are intended for single-use only.

The purpose of this submission is to implement six additional specification models: BM, AT, AY, CH, FH, and HH. The BD model was previously cleared under K152297.

The intended use, materials, manufacturing process, and sterilization method of the OBS/Biokey Anchorage Screw for BD, BM, AT, AY, CH, FH, and HH are the same. The differences are the type and dimensions (diameter and length). Different kinds of OBS/Biokey Anchorage Screw are manufactured to meet market needs. The BD model is available in diameters of 1.5, 2mm and lengths of 6, 8, 10, 12, 14mm. The BM and AT models are available in diameters of 1.6, 2mm and lengths of 6, 8, 10, 12, 14mm. The AY model is available in diameter of 1.4mm and lengths of 6, 8, 10mm. The CH, FH, and HH models are available in diameters of 1.4, 1.6, 2mm and lengths of 6, 8, 10, 12, 14mm.

5. Indications for 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.

6. Comparison of technological characteristics with the predicate device

We compared the modified device with the existing device (K152297) in the Comparison Table below.

Device Name	OBS Anchorage Screw (Existing)	OBS Anchorage Screw/Biokey Anchorage Screw (Modified)	Comparison
Applicant	BOMEI	BOMEI	Identical
510(k) Number	K152297	K202278	-
Regulation No.	21 CFR 872.3640	21 CFR 872.3640	Identical
Product Code	OAT	OAT	Identical
Trade Name	OBS Anchorage Screw	OBS Anchorage Screw Biokey Anchorage Screw	Different Add new trade name
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)	Identical

Device Name	OBS Anchorage Screw (Existing)	OBS Anchorage Screw/Biokey Anchorage Screw (Modified)	Comparison
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.	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.	Identical
Model	BD	BD, BM, AT, AY, CH, FH, HH	Different Add new six specifications
Sterility	Supplied non-sterile; steam sterilize before use	Supplied non-sterile; steam sterilize before use	Identical
Type	Square collar, Mushroom head, None/Round/Slot hole (BD)	Square collar, Mushroom head, None/Round/Slot hole (BD) Hexagonal collar, Mushroom head, None/Round/Slot hole (BM) Hexagonal collar, Oval head, None/Round/Slot hole (AT) Hexagonal collar, Slight head, None/Round hole (AY)	Different

		Cap head, None/Round/Slot hole (CH) Flat head, None/Round/Slot hole (FH) Hook head, None/Round/Slot hole (HH)	
Length (mm)	8, 10, 12, 14	6, 8, 10, 12, 14	Different Add length of 6mm
Diameter (mm)	1.5, 2	1.4, 1.5, 1.6, 2	Different Add diameters of 1.4mm, 1.6mm

Device Name	OBS Anchorage Screw (Existing)	OBS Anchorage Screw/Biokey Anchorage Screw (Modified)	Comparison
Non-thread region (mm)	0mm	0, 2, 4mm	Different Add non-thread region lengths of 2mm, 4mm (except AY) In the non-thread region, there is no pitch on the screw.
Energy sources	Non-active implantable devices	Non-active implantable devices	Identical
Where used	Dental practices	Dental practices	Identical
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.	Identical

Device Name	OBS Anchorage Screw (Existing)	OBS Anchorage Screw/Biokey Anchorage Screw (Modified)	Comparison
Biocomp. Testing	ISO 10993-5 ISO 10993-10 ISO 10993-11	ISO 10993-5 ISO 10993-10 ISO 10993-11	Identical
Sterilization Validation Testing	ISO 11737-1, ISO 11737-2, ISO 17665-1, ISO 17665-2, AAMI/ANSI ST79 for steam sterilization	ISO 11737-1, ISO 11737-2, ISO 17665-1, ISO 17665-2, AAMI/ANSI ST79 for steam sterilization	Identical
Mechanical Performance Testing	ASTM F543	ASTM F543	Identical

Device Name	OBS Anchorage Screw (Existing)	OBS Anchorage Screw/Biokey Anchorage Screw (Modified)	Comparison

7. Performance data

- Non-clinical performance testing

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

- Biocompatibility testing in accordance to ISO 10993-5, ISO 10993-10, and ISO 10993-11 and referenced from K152297:
  - Cytotoxicity: ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity
  - Sensitization and Irritation: ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
  - Systemic toxicity: ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- Sterilization validating testing in accordance to ISO 11737-1, ISO 11737-2, ISO 17665-1, ISO 17665-2, and AAMI/ANSI ST79 for steam sterilization and referenced from K152297:
  - ISO 11737-1 Sterilization of medical devices – Microbiological Methods Part 1: Determination of the population of microorganisms on product, 2ed
  - 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
  - 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
  - ISO 17665-2 Sterilization Of Health Care Products - Moist Heat - Part 2: Guidance On The Application Of ISO 17665-1
  - 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 in accordance to ASTM F543 used comparatively to demonstrate

substantial equivalence.

- ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws

- Animal Studies
  - None
- Clinical Studies
  - None

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

8. Conclusions

In comparison to the legally marketed device, the OBS/Biokey Anchorage Screw has the same intended use, materials, manufacturing process, and sterilization method. The differences between the subject device and the predicate device are the type and dimensions (diameter and length).
However, testing data such as mechanical performance testing provided in the submission show that these differences do not raise issues in performance.
Based on the information provided in this premarket notification, BOMEI concludes that the OBS/Biokey Anchorage Screw is substantially equivalent to the predicate device.