April 28, 2022

Craniofacial Technologies, Inc.
% Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group
3419 Denny Street
Pittsburgh, Pennsylvania 15201

Re: K202691
Trade/Device Name: Ortholock Anchorage Devices
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: March 25, 2022
Received: March 28, 2022

Dear Michael Nilo:

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 I. 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)*
K202691

Device Name
Orthlock Anchorage Devices

Indications for Use *(Describe)*
The Orthlock Anchorage Devices are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.

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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510k Summary
Ortholock Anchorage Devices
Prepared: April 28, 2022

Name and Address: Craniofacial Technologies Inc.
98 Buckskin Rd
West Hills, California 91307
Contact Person: Kevin Kaveh
Email: kevin@craniofacialtech.com
Telephone: (818)-282-6677

Name of device: Ortholock Anchorage Devices
Classification Name: orthodontic implants
CFR: 21 CFR 872.3640
Primary Product Code: OAT

Device Description:
The Ortholock anchorage device is an implantable self-drilling orthodontic microimplant intended to provide a temporary fixed anchorage point to facilitate orthodontic treatment. The device interacts with an appliance accessory, which includes two insertion locations for Ortholock and a tube for the attachment of general orthodontic appliances.

The devices are made from Ti6Al4V and their surfaces are anodized so the different lengths can easily be visually identified.

The following table describes the two versions of Ortholock:

Part. No.	Total Length	Neck Length	Diameter	Color
OL011	11.5mm	2.2mm	1.8mm	Green
OL013	13.5mm	4.2mm	1.8mm	Blue

Orthodontic microimplants are used for the anchorage of orthodontic appliances to treat malpositioned teeth. Ortholock is inserted in the hard palate into each of the two insertion apertures of the appliance accessory with corresponding internal threads for Ortholock's external locking threads. The appliance accessory includes a tube for the attachment of 1.1 mm orthodontic round wire. Ortholock is intended for temporary use during orthodontic treatment. The device is single use only.

Indications for Use: The Ortholock Anchorage Devices are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.

Testing Summary: Ortholock was compared to the primary predicate device in bench testing using protocols based on ISO 19023 and ASTM F543-17 for torsional properties, driving torque, axial pullout

strength, and self-tapping performance. The test results of these tests demonstrated that similar mechanical performance values could be achieved by the subject and primary predicate device.

Ortholock Anchorage Device is provided Non-Sterile (Steam sterilized by end user). Sterilization by moist heat was validated by ISO 17665-1.

Biological assessment has been performed according to ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and to the FDA Guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff", for the subject devices. Cytotoxicity testing according to ISO 10993-5 Biological Evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity.

Primary Predicate Device: The C-Type, CT Type and Special Type Orthodontic Anchor Screws (K063495) Biomaterials Korea

Reference Device:
PSM Medical BENEFIT Screw – (K110392)

Substantial Equivalence:

	Subject Device	Primary Predicate Device	Reference Device
Name	Ortholock Anchorage Devices Craniofacial Technologies (K202691)	The C-Type, CT Type and Special Type Orthodontic Anchor Screws K063495 Biomaterials Korea	PSM Medical BENEFIT Screw – (K110392)
Indications for Use	The Ortholock Anchorage Devices are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.	Intended for use as a temporary anchor for orthodontic treatment	The PSM LOMAS / BENEFIT Screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. Screws are intended for single use only.

Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Surface Treatment	Anodized	Anodized	Anodized
Design			
Body Diameter	1.8mm	1.8mm	2.0mm and 2.3mm
Head Structure	Externally Threaded Head for the attachment of orthodontic appliances	Bracket head for the attachment of orthodontic appliances (extra long neck also facilitates the attachment of orthodontic appliances)	Internally Threaded Head for the attachment of orthodontic appliances
Length	Threaded Body: 7.4mm Smooth Neck: 2.2mm and 4.2mm Head: 1.9mm Overall Length: 11.5mm and 13.5mm	Threaded Body: 7mm Smooth Neck: 4mm and 6mm Head: 2.1mm Overall Length: 13.1mm and 15.1mm	Available in threaded lengths of 7mm, 9mm, 11mm, and 13mm.
Placement Locations	Suitable locations for Ortholock placement include the paramedian or midsagittal region of the hard palate and the anterior palate. Do not place the Ortholock Anchorage Device screws in the sutures of people with developing bone or sutures that are not completely fused.	Multiple locations in the oral cavity.	Multiple locations in the oral cavity.
Self-Drilling	Yes	Yes	Yes

Non-Sterile (Sterilized before use)	Yes	Yes	Yes
Sterilization Validation Provided	Yes	Yes	Yes
Principles of Operation	Orthodontic implants are used for the anchorage of orthodontic appliances to treat malpositioned teeth. The head of the screw contains an external thread for the attachment of orthodontic appliances for temporary use during orthodontic treatment.	Orthodontic implants are used for the anchorage of orthodontic appliances to treat malpositioned teeth. The head of the microimplant contains a slot feature for the attachment of orthodontic appliances for temporary use during orthodontic treatment.	Orthodontic implants are used for the anchorage of orthodontic appliances to treat malpositioned teeth. The head of the PSM Medical Benefit microimplant contains an internal thread for the attachment of orthodontic appliances for temporary use during orthodontic treatment.

Conclusion: Ortholock Anchorage Screws are substantially equivalent to the Biomaterials Korea C-Type, CT Type and Special Type Orthodontic Anchor Screws because they have substantially similar indications, are intended for the same use, are made from the same materials, and have the same principle of operations. They are both sold non-sterile to be sterilized by the user, both are self-drilling, and have similar testing including sterilization validation and bench testing. Comparative bench testing shows their mechanical characteristics are similar. Their diameters, lengths, smooth neck lengths, and head sizes are similar. The head design of the subject device is similar to the head design of the reference device– the PSM Medical BENEFIT Screw. In both the proposed device and reference device, orthodontic appliances intended for the same use are firmly anchored to the screw head with the use of threads and similar appliance accessories.