December 17, 2020

Blue Sky Bio, LLC
℅ Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K201919
Trade/Device Name: Blue Sky Bio TAD
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: November 12, 2020
Received: November 19, 2020

Dear Juan Tezak:

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

4. Indications for Use Statement

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)*

K201919

Device Name

Blue Sky Bio TAD

Indications for Use *(Describe)*

The proposed Blue Sky Bio TAD is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for a single use only. For use in adolescents greater than age 12 and adults.

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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5. 510(k) Summary

K201919
Blue Sky Bio, LLC
Blue Sky Bio TAD
December 17th, 2020

ADMINISTRATIVE INFORMATION

Applicant	Blue Sky Bio, LLC 800 Liberty Dr. Libertyville, IL 60048 Phone: +1 718-376-0422
Establishment Registration Number	3003402534
Official Contact	Sharon Nichols, Regulatory Representative
Representative/Consultant	Juan Tezak Carlos Marín Compliance4Devices 118 W Prive Cr. Delray Beach Fl, 33445 Tel: +1 561-789-2411 e-mail: compliance4devices@gmail.com

DEVICE AND CLASSIFICATION NAME

Device Trade Name:	**Blue Sky Bio TAD**
Common Name:	Bone Screw, Orthodontic
Classification Regulation:	21 CFR 872.3640
Classification Name:	Endosseous dental implant
Device Classification:	Class II
Classification Panel:	Dental
Product Code:	OAT

PREDICATE DEVICES INFORMATION

Primary predicate
K113650, OrthoFix Screw

Reference device
K033767, Dual Top Anchor System Screw
K102034, Blue Sky Bio Dental Implant System

Intended Use

The proposed Blue Sky Bio TAD is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for a single use only. For use in adolescents greater than age 12 and adults.

Device Description

The Blue Sky Bio TAD is fabricated from titanium Alloy without surface treatment, which meets the material requirements specified in the standard ASTM F-136-08. The head on the proximal portion of the screw incorporates a recess, which provides an option for the orthodontist to pass through a wire and tie it in the neck of the Blue Sky Bio TAD in the orthodontic treatment. Distal to the recess is a square indentation that is used as a screw head.

The smooth neck distal to the proximal head employs a hole through which a wire can be passed to fix the mandible and maxilla in orthodontic treatment. Distal to the neck is the collar, which has a tapered design to protect the soft tissue. The distal portion of the proposed Blue Sky Bio TAD is threaded for quick insertion and provides stability and bio-mechanic retention once the screw is fully inserted. The distal tip of the screw is machined with high precision manufacturing.

Equivalence to Marketed Devices

Blue Sky Bio TAD is substantially equivalent to the predicated device and reference devices. In further support of a substantial equivalence determination, here-under is a comparison chart with the submitted device, the predicate device and reference device.

Feature	Subject Device	Predicate Device	Reference device	Reference device
	Blue Sky Bio, LLC Blue Sky Bio TAD K201919	BonaFix Surgical & Dental Implants, LLC OrthoFix Screw K113650	Jeil Medical Corp. Dual Top Anchor System Screw K033767	Blue Sky Bio, LLC Blue Sky Bio Dental Implant System K102034
Material	Medical Grade Titanium Alloy ASTM 136	Medical Grade Titanium Alloy ASTM 136	Medical Grade Titanium Alloy ASTM 136	Medical Grade Titanium Alloy ASTM 136
Surface treatment	No	No	No	Yes
Design Screw Head	Incorporates a recess	Incorporates a recess	Incorporates a recess	
Design Neck	Through hole	Through hole	Through hole	
Design Collar	Tapered	Tapered	Tapered	
Principle of Operation	Provide fixed anchorage for orthodontic movement of teeth	Provide fixed anchorage for orthodontic movement of teeth	Provide fixed anchorage for orthodontic movement of teeth	
Diameter	1.6 and 1.8 mm	1.6 and 1.8 mm	1.4, 1.6 & 2.0 mm	
Length	6 and 9mm	6 and 9mm	6, 8, 10 & 12 mm	
Indications for Use	The proposed Blue Sky Bio TAD is	The device is intended to provide	The device is intended to provide	

	intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for a single use only. For use in adolescents greater than age 12 and adults.	fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. For use in adolescents greater than age 12 and adults	fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. For use in adults over the age of 12	
Single use	Yes	Yes	Yes	Yes
Sterility	Provided sterile and Non-sterile	Provided sterile	Provided Non-sterile	Provided sterile
Packaging	Packaged in as single units sealed in a plastic pouch (polyethylene terephthalate/low density polyethylene, PET/LDPE) with a peelable chevron seal, and each sealed pouch is then inserted into a single unit plastic envelope (polyethylene terephthalate glycol-modified, PETG).			Packaged in as single units sealed in a plastic pouch (polyethylene terephthalate/low density polyethylene, PET/LDPE) with a peelable chevron seal, and each sealed pouch is then inserted into a single unit plastic envelope (polyethylene terephthalate glycol-modified, PETG).

Blue Sky Bio TAD is substantially equivalent in design, function, operating principle, material, sizes, and Indications for Use to predicate device OrthoFix Screw (K113650) and reference device Dual Top Anchor System Screw (K033767).
The subject device has two presentations, sterile and non-sterile. Regarding to sterile product, subject device is substantially equivalent to predicate device OrthoFix Screw (K113650); and to non-sterile product is substantially equivalent to the reference device Dual Top Anchor System Screw (K033767).
The packaging of the subject device is going to be the same in design, materials and dimensions as the reference Blue Sky Bio Implant System (K102034). The device reference packaging validation to maintain a sterile barrier for the entirety of the proposed shelf life was applied.

Non-Clinical Testing Summary
Non-clinical performance tests are:

- Axial pull-out strength testing
  According to the test standard (ASTM F543), Pull-out strength testing is performed for the effectiveness of the mechanical design of the orthodontic mini implant and its elimination.
- Peak Torque Value
  The test was performed according to Article by Drs. Jolley and Chung Published in the Journal of Clinical Orthopedics.
- Insertion Torque Test
  The test was performed in order to measure the torque required for insertion of the Blue Sky Bio TAD anchor, in the worst-case scenario version into a standard material, and to validate the surgical protocol provided in the instructions for use.
- Sterilization
  The subject device TAD implants are provided sterile and non-sterile.
  The TAD implants that are provided sterile has been validated according to ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.
  The TAD implants that are provided non-sterile are to be sterilized by the end user. The recommended moist heat (steam)sterilization cycle has been validated according to 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, and ISO 17665-2 Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1.
- Shel Life
  All implant, sterile and non-sterile, are packaged in as single units sealed in a plastic pouch (polyethylene terephthalate/low density polyethylene, PET/LDPE) with a peelable chevron seal, and each sealed pouch is then inserted into a single unit plastic envelope (polyethylene terephthalate glycol-modified, PETG).
  The sterile barrier shelf life for the subject device was determined by the following aging methods: Accelerated method and Real-time shelf life. For accelerated and real time, package integrity of the sterile barrier was confirmed by the following test method: Distribution testing according to ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems; Seal strength testing according to ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials; and Sterile barrier system Integrity by dye penetration testing.
- Biocompatibility
  The subject device implants are made of titanium alloy conforming to ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). This titanium alloy is commonly used in endosseous dental implants and abutments, with a history of safe use, and is the same material used for predicate device OrthoFix previously cleared in K113650. The subject device is manufactured in the same facilities and use the same manufacturing process as used from Blue Sky Bio devices and components previously cleared. Therefore, no new biocompatibility

testing has been performed as the subject device is identical to the predicate devices and reference devices with regards to materials and processing.

- Pyrogenicity
  Blue Sky Bio LLC, conducts Pyrogenicity test to meet pyrogen limit specifications. This test will be conducted on every batch.

Clinical Testing Summary

Clinical testing was not required to demonstrate the substantial equivalence of the Blue Sky Bio TAD to its predicate device.

Conclusion

- The subject device is made of the same materials and is identical in regards to dimensions and characteristics as the primary predicate device.
- The subject device is manufactured from Titanium Alloy that is widely used in this kind of endosseous dental implant systems.
- The subject device is manufactured in the same facilities using the same manufacturing processes were Blue Sky Bio LLC manufacture others implants and components that were previously cleared by the FDA.
- The subject device and predicate device are substantially equivalent in their intended use, technological characteristics and performance.

We conclude that the Blue Sky Bio TAD is substantial equivalent to the predicate devices listed above.