August 12, 2019

Blue Sky Bio, LLC.
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K190491
Trade/Device Name: Blue Sky Bio Zygomatic Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 18, 2019
Received: July 19, 2019

Dear Kevin Thomas:

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,

for Srinivas Nandkumar, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190491

Device Name

Blue Sky Bio Zygomatic Implant System

Indications for Use *(Describe)*

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

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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K190491

510(k) Summary

Blue Sky Bio, LLC

Blue Sky Bio Zygomatic Implant System

February 27, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 800 Liberty Drive Libertyville, IL 60048 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Michele Kupcso, Vice President of RA/QA
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device:
K153064, Blue Sky Bio Zygomatic Implant System, Blue Sky Bio, LLC

Reference Device:
K151909, Noris Medical Zygomatic Dental Implant System, Noris Medical Ltd.

INDICATIONS FOR USE STATEMENT

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DEVICE DESCRIPTION

The purpose of this submission is to expand the Blue Sky Bio Zygomatic Implant System cleared in K153064. This submission includes abutments with two interface connection designs for attachment to the previously cleared zygomatic implants: an internal hexagon connection (with a 45° bevel) and a tapered internal hexagon connection (with a 12° taper). The internal hexagon connection abutments are provided in platforms of 3.5 mm and 4.5 mm. The tapered internal hexagon connection abutments are provided in platforms of 3.5 mm (NP) and 4.3 mm (RP). All subject abutments have an angulation of 45° and are for support of screw-retained overdenture prosthetic restorations. Except for the angulation, the subject device abutments have the same designs as corresponding abutments cleared in K153064. The abutment screws compatible with the subject device abutments were cleared in K060957 and K102034. The subject device abutments are made of titanium alloy conforming to ASTM F136. The previously cleared abutment screws also are made of material conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: sterilization validation according to ISO 17665-1 and ISO 17665-2 (referenced from K153064 and K073713); biocompatibility (referenced from K153064); engineering analysis; dimensional analysis; and dynamic compression-bending testing of the 45° NP (3.5 mm platform) abutment on a compatible tapered internal hexagon connection 4.3 mm body diameter implant according to ISO 14801. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in intended use to the primary predicate K153064 and to the reference device K151909. All are intended for use in the maxilla to provide functional and esthetic rehabilitation of the edentulous maxilla. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference device.

The subject device and the primary predicate K153064 have identical Indications for Use Statements (IFUS). The subject device IFUS is similar to that of the reference device K151909; minor differences include wording in the K151909 IFUS regarding standard dental implants and the use with removable prosthetics with zygomatic implants. These minor differences do not impact safety or effectiveness.

The subject device is a line extension to the primary predicate device K153064. The subject device abutments have the same designs, platforms diameters, and dimensions (except for angulation) as the abutments cleared in K153064. The subject device abutments are angled 45°, whereas the abutments cleared in K153064 are angled 17° and 30°. The risks associated with this increase in angulation has been mitigated by mechanical testing (discussed below).

The subject device abutments are made from the same material, are manufactured using the same processes, are packaged the same, and are to be sterilized by the same method (moist heat) as the abutments cleared in K153064. The subject device abutments are compatible exclusively with the zygomatic implants cleared in K153064.

The reference device K151909 is for support of the 45° angulation of the subject device abutments. K151909 includes 45° angled abutments made of the same material, with a similar internal hex connection, and intended for screw-retained multi-unit restorations as the subject device abutments.

The subject device abutments are made of titanium alloy conforming to ASTM F136, the same material as abutments cleared in K153064.

Mechanical performance testing of the subject device was performed according to ISO 14801 and included static compression and compression fatigue testing. Worst-case constructs consisted of the subject device 45° Angled Multiunit BIO | Max Abutment NP abutment and the previously-cleared compatible Bio | Max NP 4.3 mm body diameter implant (with tapered internal hexagon connection and cleared in K102034). The fatigue limit data demonstrated that constructs of the subject device abutments in combination with the previously-cleared compatible zygomatic implants, and used according to the proposed labeling, have sufficient strength for their intended use.

The subject device abutments and the abutments in K153064 and K151909 are supplied nonsterile and are to be sterilized by moist heat (steam) by the end user. The subject device abutments are to be sterilized by the identical moist heat cycle as the cycle cleared in K153064.

CONCLUSION

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, and reference device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence

Comparison	Subject Device Blue Sky Bio Zygomatic Implant System Blue Sky Bio, LLC	Primary Predicate Device K153064 Blue Sky Bio Zygomatic Implant System Blue Sky Bio, LLC.	Reference Device K151909 Noris Medical Zygomatic Dental Implant System Noris Medical Ltd.
Indications for Use Statement	Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.
Reason for Predicate / Reference Device	Not applicable	Compatible implants and abutment screws; Same abutment designs	45° abutment angle
Product Code	NHA	DZE, NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous maxilla	Functional and esthetic rehabilitation of the edentulous maxilla
Designs			
Implant Designs	*(Compatible previously cleared implants, not a subject of this submission)* Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Partially threaded root-form implants for placement into the zygoma
Implant Diameters	*(Compatible previously cleared implants, not a subject of this submission)* Internal hex connection: 4.7 mm, tapering to apex Tapered internal hex connection: 4.3 mm and 5.0 mm, tapering to apex	Internal hex connection: 4.7 mm, tapering to apex Tapered internal hex connection: 4.3 mm and 5.0 mm, tapering to apex	4.2 mm (coronal) taper to 3.5 mm (apical)
Lengths	*(Compatible previously cleared implants, not a subject of this submission)* 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm	35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm	35 mm – 57.5 mm
Abutment Designs	Internal hex with 12° taper Internal hex with 45° bevel	Internal hex with 12° taper Internal hex with 45° bevel	Internal hex with 45° bevel
Prosthesis Attachment	Screw-retained	Screw-retained	Screw-retained
Restoration	Multi-unit	Multi-unit	Multi-unit
Abutment-Implant Platform Diameters	Internal hex connection: 3.5 mm, 4.5 mm Tapered internal hex connection: 3.5 mm (NP) and 4.3 mm (RP)	Internal hex connection: 3.5 mm, 4.5 mm Tapered internal hex connection: 3.5 mm (NP) and 4.3 mm (RP)	Internal hex connection: 3.75mm
Abutment Angles	45°	17°, 30°	45°
Abutment-Implant Interface	Internal hex; No angulation at head of implant	Internal hex; No angulation at head of implant	Internal hex; No angulation at head of implant
Materials			
Implants	*(Compatible previously cleared implants, not a subject of this submission)* Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136
Abutments	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136
Abutment Screws	*(Compatible previously cleared screws, not a subject of this submission)* Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136
How Provided			
Sterilization Status/Method			
Implants	*(Compatible previously cleared implants, not a subject of this submission)* Sterile/gamma irradiation	Sterile/gamma irradiation	Sterile/gamma irradiation
Abutments	Nonsterile/ to be moist heat sterilized by end user	Nonsterile/ to be moist heat sterilized by end user	Nonsterile/ to be moist heat sterilized by end user
Abutment Screws	*(Compatible previously cleared screwss, not a subject of this submission)* Nonsterile/ to be moist heat sterilized by end user	Nonsterile/ to be moist heat sterilized by end user	Nonsterile/ to be moist heat sterilized by end user
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use