



Food and Drug Administration
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April 29, 2016

Blue Sky Bio, LLC
c/o Kevin A. Thomas, Ph.D.
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K153064

Trade/Device Name: Blue Sky Bio Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 31, 2016
Received: March 31, 2016

Dear Dr. 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. 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); 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), 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,

 Tina Kiang
-S

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

Indications for Use

510(k) Number (if known)

K153064

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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510(k) Summary
Blue Sky Bio, LLC
Blue Sky Bio Zygomatic Implant System

April 28, 2016

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate device:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

Reference predicate devices:

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC

K093562, Zygomatic Implant System, Southern Implants, Inc.

INTENDED USE

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

Blue Sky Bio Zygomatic Implant System submission includes threaded root-form dental implants and mating abutments designed for placement into the zygomatic bone. The zygomatic implants are provided with an internal hexagon connection and a tapered internal hexagon interface for connection to the subject abutments. The internal hexagon connection implants are provided with a body diameter of 4.7 mm and platform diameters of 3.5 mm and 4.5 mm. The tapered internal hexagon connection implants are provided with a body diameter of 4.3 mm and a narrow platform (NP) connection, and with a body diameter of 5.0 mm with a regular platform (RP) connection. All implants are provided in multiple overall threaded lengths ranging from 35 mm to 55 mm. This submission includes mating abutments with platform diameters of 3.5, 4.3, and 4.5 mm, and each abutment diameter is provided with 17° and 30° of angulation. All subject device abutments are for support of screw-retained overdenture prosthetic restorations. The abutment screws compatible with the subject device abutments were cleared in K060957 and K102034. The subject device zygomatic implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. 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: biocompatibility (referenced from K102034 and K060957), engineering analysis, dimensional analysis, and dynamic compression-bending testing of the Taper Hex 4.3 mm body diameter implant with the NP platform according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Blue Sky Bio, LLC submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA’s regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC;

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC; and

K093562, Zygomatic Implant System, Southern Implants, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K141777 is provided in the following table.

	Subject Device	Primary Predicate Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Indications for Use	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.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. 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. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Implants		
Design	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments
Implant body Ø and Platform Ø	Internal hex connection Implant body Ø: 4.7 mm Abutment platform Ø: 3.5 mm, 4.5 mm (implant body tapers at apical portion)	External hex and Morse taper Implant body Ø: 4.4 mm tapering to 3.9 mm Platform Ø: 4.1 mm
	Tapered internal hex connection Implant body Ø: 4.3 mm with NP 3.5 mm abutment platform Implant body Ø: 5.0 mm with RP 4.3 mm abutment platform (implant body tapers at apical portion)	
Implant Lengths	All implants: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm	External hex: 30, 35, 40, 45, 47.5, 50, 52.5 mm Morse taper: 30, 35, 40, 42.5, 45, 47.5, 50, 52.5 mm
Implant-Abutment Interface		
Type	Internal hex with 12° taper Internal hex with 45° bevel	External hex Morse taper
Implant body-abutment connection angle	n/a	45°
Abutments		
Platform Diameter	Internal hex connection: 3.5 mm, 4.5 mm Tapered internal hex connection: 4.3 mm	4.1 mm
Abutment Angle	17°, 30°	0° (straight)

	Subject Device	Primary Predicate Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Materials		
Implants	Ti-6Al-4V	F67 unalloyed titanium, grade 4
Implant Surface	Grit blasted and acid etched	Machined
Abutments	Ti-6Al-4V	F136 Ti-6Al-4V ELI
Abutment Screws	Ti-6Al-4V	External hex: F136 Ti-6Al-4V ELI

The subject device and the primary predicate K141777 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K141777 have similar designs and dimensions, including lengths appropriate for zygomatic placement.

The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement. The subject zygomatic implants are provided in a range of implant body diameters (maximum endosseous thread diameters) of 4.3 mm to 5.0 mm, the same as the predicate implants cleared in K102034 and K060957. The smaller subject device implant body (4.3 mm diameter) as compared to the primary predicate K141777 (4.4 mm diameter) is supported by the reference predicate K093562 (4.05 mm body diameter), and by and dynamic compression-bending testing according to ISO 14801.

The subject device implants are provided in the same range of overall lengths as the primary predicate K141777 (35 mm to 52.5 mm), and the subject device 55 mm length implant is supported by the reference predicate K093562.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The subject device abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. The subject device abutments are substantially equivalent to the abutments cleared in K102034 and K060957 in terms of implant-abutment connections, platform diameters, angulation, and materials. The subject abutments are to be used with compatible abutment screws cleared in K102034 and K060957.

Differences between the subject device and the primary predicate K141777 include the location of angulation correction (subject device includes abutments with angulation, versus K141777 implant designs included angulation at the abutment-implant connection), and the amount of angulation (subject device 17° or 30°, versus K141777 only 45°). These differences between the subject device and the primary predicate are supported by dynamic compression-bending testing according to ISO 14801. Dynamic testing of worst case subject device constructs consisting of the smallest diameter implant (Taper Hex 4.3 mm body diameter) and largest angulation (30°)

demonstrated fatigue performance substantially equivalent to that of the primary predicate K141777.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, the same as these components cleared in K102034 and K060957. The endosseous surface finish of the subject device implants is the same as the predicate implants cleared in K102034 and K060957.

The subject device implants have similar packaging and are sterilized using the same materials and processes as described in K102034 and K060957. The subject device abutments are provided nonsterile in similar packaging and are to be sterilized using the same processes as described in K102034 and K060957.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

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