June 30, 2022

Blue Sky Bio, LLC
Albert Zickmann
Vice President of Product Development
800 Liberty Dr.
Libertyville, Illinois 60048

Re: K212785
Trade/Device Name: Blue Sky Bio Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 1, 2022
Received: June 3, 2022

Dear Albert Zickmann:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K212785

Device Name

Blue Sky Bio Implant System

Indications for Use *(Describe)*

Blue Sky Bio Multi One Implant System is intended for surgical placement in the bone of the upper or lower jaw to provide support for prosthetic devices to restore chewing function. Implants may be used with single-stage or two-stage procedures. They can be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Multi One Implants are indicated for multi-unit restorations in splinted applications. Blue Sky Bio Multi One Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

Blue Sky Bio PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Blue Sky Bio, LLC

Blue Sky Bio Implant System – K212785

June 30, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 800 Liberty Dr. Libertyville, IL 60048 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Albert Zickmann Vice President of product development Telephone +1 718-376-0422 Email: azickmann@blueskybio.com

DEVICE NAME AND CLASSIFICATION

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

PREDICATE DEVICE INFORMATION

Primary predicate devices:

K190958, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

Reference devices:

K061319, Spectra Implant System, Implant Direct, LLC

K191250, PEEK Abutments, Southern Implants, Inc

K163634, External Hex Implant, Southern Implants, (Pty) Ltd.

K190491, Blue Sky Bio Zygomatic Implant System, Blue Sky Bio, LLC;

K153064, Blue Sky Bio Zygomatic Implant System, Blue Sky Bio, LLC;

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

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

K160119, NobelSpeedy Groovy, Nobel Biocare AB and

K071235, Zimmer One Piece, 3.0 Angled, Zimmer Dental, Inc.

Blue Sky Bio Dental Implant System

INDICATIONS FOR USE

Blue Sky Bio Multi One Implant System is intended for surgical placement in the bone of the upper or lower jaw to provide support for prosthetic devices to restore chewing function. Implants may be used with single-stage or two-stage procedures. They can be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Multi One Implants are indicated for multi-unit restorations in splinted applications. Blue Sky Bio Multi One Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

Blue Sky Bio PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

DEVICE DESCRIPTION

Blue Sky Bio BIO|MAX MULTI ONE Implants include a one-piece implant/abutment construct provided with body diameters of 3.0 mm to 4.3 mm, in multiple lengths ranging from 10 mm to 20 mm. They are provided with a head angulation of 17°, 30°, or 45°. Multi One Implants with body diameters of 3.5 mm and 4.3 mm, in lengths ranging from 10 mm to 20 mm with a 45° angulation are indicated for the pterygoid region only. Implant body diameters of 3.0 mm and 3.25 mm are only intended for the alveolar ridge and not intended for placement in the pterygoid region.

Blue Sky Bio BIO|LONG implants and BIO|MAX MULTI ONE LONG implants include implant lengths designed for placement into the posterior maxillary region, including the pterygoid plate. The implants have one of three connections, an internal hexagon interface (3.5 mm platform), a tapered internal hexagon interface (NP platform) or a Multi One one-piece design. The implants are provided with a body diameter of 3.7 mm to 5.0 mm in implantable lengths ranging from 20 mm to 25 mm. BIO|MAX MULTI ONE LONG implants are provided with a head angulation of 17°, 30°, or 45°. Blue Sky Bio BIO|LONG implants and BIO|MAX MULTI ONE LONG implants are intended to be used with the TILT procedure in the maxilla as shown in the clinical literature. Implants with 45° angulation are indicated for the pterygoid region only. BIO|INTERNAL HEX LONG implants (3.5 mm Platform) are for use with abutments of up to 30° only.

Details of specific implant diameters and lengths are outlined in the table below. Abutments and abutment screws compatible with the BIO|LONG Implants were cleared in K060957, K102034 and K190491.

Blue Sky Bio PEEK abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation. Subject device PEEK abutments are provided with two implant/abutment connections, BIO|INTERNAL HEX (3.5 mm Platform) and BIO|MAX (NP).

The subject device implants 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).* Previously cleared abutments and abutment screws are made of material conforming to ASTM F136. Temporary PEEK abutments are made from TECAPEEK conforming to

ASTM F2026 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.*

BIO|MAX MULTI ONE (one-piece)	**10**	**11.5**	**13**	**16**	**18**	**20**
Ø 3.0 mm Straight	X	X	X	X		
Ø 3.0 mm 17°	X	X	X	X		
Ø 3.0 mm 30°	X	X	X	X		
Ø 3.25 mm Straight	X	X	X	X	X	X
Ø 3.25 mm 17°	X	X	X	X	X	X
Ø 3.25 mm 30°	X	X	X	X	X	X
Ø 3.5 mm 45° (pterygoid only)	X	X	X	X	X	X
Ø 4.3 mm 45° (pterygoid only)	X	X	X	X	X	X
BIO|LONG Implants				**20**	**22.5**	**25**
BIO|INTERNAL HEX LONG						
Ø 3.7 mm				X	X	X
Ø 4.3 mm				X	X	X
Ø 5.0 mm				X	X	X
BIO|MAX LONG						
Ø 3.7 mm				X	X	X
Ø 4.3 mm				X	X	X
Ø 5.0 mm				X	X	X
BIO|MAX MULTI ONE LONG				**20**	**22.5**	**25**
Ø 3.7 mm 17°				X	X	X
Ø 3.7 mm 30°				X	X	X
Ø 3.7 mm 45° (pterygoid only)				X	X	X
Ø 4.3 mm 17°				X	X	X
Ø 4.3 mm 30°				X	X	X
Ø 4.3 mm 45° (pterygoid only)				X	X	X
Ø 5.0 mm 17°				X	X	X
Ø 5.0 mm 30°				X	X	X
Ø 5.0 mm 45° (pterygoid only)				X	X	X

NON-CLINICAL PERFORMANCE TEST DATA

Fatigue testing was performed according to the requirements of ISO 14801:2016, Dentistry – Implants – Dynamic loading test for Endosseous Dental Implants and following FDA Guidance, *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.*

The subject device titanium implants are manufactured in the same facilities using the same materials, manufacturing processes as used for the sponsor's own implants as previously cleared in K190491, K102034 and K060957.

Blue Sky Bio Dental Implant System

The subject titanium implant devices have the same nature of body contact, contact duration, material formulation as the sponsor's own implants as previously cleared in K190491, K102034 and K060957.

Cytotoxicity testing was performed on representative Temporary PEEK abutments (ASTM F2026-17) according to ISO 10993-1, ISO 10993-5, ISO 10993-12.

The packaging for the subject device is the identical to the sponsor's own prior clearances as referenced in K102034 and K073713 in which accelerated aging testing was presented and leveraged for the subject devices. Test results and Sterilization Validations performed for the sponsor's own reference devices is also leveraged demonstrate suitable sterilization of the subject device sterile components with demonstration of a sterility assurance level (SAL) of 10^{-6}.

Pyrogenicity information provided is based on FDA Guidance on *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016. The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

End-user sterility validation was conducted according to ISO 17665-1 and ISO 17665-2 for subject Temporary PEEK Abutments.

Non-clinical worst-case MRI review to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the subject device components and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

CLINICAL LITERATURE

Clinical Literature is submitted in support of the subject implant placement in the pterygoid region and implant dimensions in this submission. The subject device dimensions with Ø3.5 – Ø5.0 mm with lengths of 10 mm – 25 mm are substantially equivalent for pterygoid placement.

Blue Sky Bio BIO|MAX MULTI ONE Implants, Blue Sky Bio BIO|LONG implants, and BIO|MAX MULTI ONE LONG implants are intended to be used with the TILT procedure in the maxilla as shown in the clinical literature and as shown for the predicate devices in publicly available literature. Implants with 45° angulation are indicated for the pterygoid region only.

The table below outlines the clinical literature submitted in the premarket notification submission for a determination of substantial equivalence in support of the Blue Sky Bio BIO|MAX MULTI ONE Implants, Blue Sky Bio BIO|LONG implants, and BIO|MAX MULTI ONE LONG implants. These articles provide information to show that long implants used clinically in the TILT procedure and in the pterygoid region are clinically safe and effective for their intended use.

Implants from 10 – 25 mm in length placed at angles 15°- 45° are used in both the TILT procedure and in the pterygoid region with a similar success rate to standard implants. Placement in the pterygoid region is preferable to placement of zygomatic implants due to the greater bone to implant contact and the reduced fulcrum force on the bone. Literature also supports maxillary placement with the TILT procedure or pterygoid placement to avoid additional procedures such as sinus lift and grafting in areas of an atrophic maxilla. BIO|MAX MULTI ONE Implants, Blue Sky Bio BIO|LONG implants, and BIO|MAX MULTI ONE LONG implants are provided in lengths of 10 mm – 25 mm and placed at an angle of 45° or less. This is within the window of the successful implants identified in the literature. Nobel Biocare, NobelSpeedy Groovy implants in lengths of 20-25 mm are identified as using the TILT procedure in the article and the

literature identified was used in support of K160119 where implants of 22 mm and 25 mm had no predicate.

Conclusion:

The subject device sizes for long implant Ø3.5 – Ø5.0 mm with lengths of 10 mm – 25 mm do not raise new questions of safety and effectiveness compared to the predicate devices and the clinical literature in the maxilla or pterygoid regions. BIO|MAX MULTI ONE Implants, Blue Sky Bio BIO|LONG implants, and BIO|MAX MULTI ONE LONG implants are provided in lengths of 10 mm – 25 mm and placed at an angle of 45° or less. This is within the window of the successful implants identified in the literature. They are shorter than the lengths placed in the zygoma which have less bone to implant contact and greater fulcrum force. Therefore, Blue Sky Bio Long Implants do not present greater risk than zygomatic implants.

Clinical Literature Summary Table

Article	Diameter	Length	Angle	Comments
1	Refers to Reference Articles	Refers to Reference Articles	45°	*A systematic review in 2011 indicated a 92% short-term survival rate. However, these baseline findings included data on machined (obsolete older surfaces) and modern micro-roughened surfaces. A more recent study focusing exclusively on implants with micro-roughened surfaces reported a 3-year survival rate of 99%.9 This was similar to another study in 2005 that reported a survival rate of 98.6%.*
2	3.75 - 4.0 mm	16 - 20 mm	15 - 60°	*"A retrospective study was performed of patients with an atrophic posterior maxilla rehabilitated with pterygoid implants between 1999 and 2010 and followed for at least 36 months after implant loading. A total of 238 titanium implants (172 anterior and 66 pterygoid) were placed in 56 patients. The 3-year overall pterygoid implant survival rate was 99%"*
3	Stated as considered but not identified in the publication	13 - 20 mm	18 - 20 mm @ 15-60° 13 - 18 mm @ 60-90° 15 - 20 mm @ 45°	*A total of 634 patients received 1.893 pterygoid implants, with a mean implant survival rate of 94.87%. The mean prevalence of implant failure was 0.056 with a 95% CI of 0.04 - 0.077. This study demonstrates that pterygoid implants can be successfully used in patients with atrophic posterior maxilla.*
4	3.75 - 4.2 mm	18 - 25 mm	30 - 55°	"Referenced literature: patient population not specifically stated in this review. Presented are 17 studies from 1992 to 2015, with total number of pterygoid implants – 2525 and average success of 91.88%."
5	3.75 - 4.2 mm	18 - 25 mm	30 - 55°	Referenced literature: patient population not specifically stated in this review. *"Pterygoid implant provides a reasonable alternative to 3D maxillary reconstruction, sinus lifts, and bone augmentation technique. Many authors have reported success rates of pterygoid implants ranging from 90% to 100% after follow-up period ranging from 1 to 12 years with minimal complications. Avoidance of a prosthetic distal cantilever with good stability fit for immediate loading is possible with this technique".*
6	3.75 mm	13 - 22 mm	not specified	3 Case reports: 37yr (F), 42 yr (M), 61 yr (F), plus literature review. Referenced literature: patient population not specifically stated in this review. *"Pterygoid implants were intended to pass through maxillary tuberosity, the pyramidal process of palatine bone and the pterygoid process of the sphenoid bone. In the literature, success rates of pterygoid implants for maxillary rehabilitation have been more than 94 to 99%."*
7	3.75 - 4.0 mm not all sizes identified	10 – 22 mm	35 - 55°	*Thirteen articles were included, reporting a total of 1053 pterygoid implants in 676 patients. The weighted average success of pterygoid implants was 90.7%; bone loss evaluated radiographically ranged between 0 and 4.5 mm. No additional complications compared with conventional implants were found, and patient satisfaction level with the prosthesis was high. Pterygoid implants have high success rates, similar bone loss levels to those of conventional implants, minimal complications and good acceptance by patients, being therefore an alternative to treat patients with atrophic posterior maxilla.*

Blue Sky Bio Dental Implant System

Article	Diameter	Length	Angle	Comments
8	3.5 & 3.75 mm listed	16 - 57 mm: (The preferred length in the pterygoid is 22-25 mm)	30 - 50°	Referenced literature: patient population not specifically stated in this review. *"Pterygoid implants were introduced by Tulasne which were intended to pass through maxillary tuberosity, the pyramidal process of palatine bone and engaging the pterygoid process of sphenoid bone. It overcomes the need for sinus lift procedures, grafting process, and, at times, even the invasive zygoma implants. The success rates of tilted and pterygoid implants for maxillary rehabilitation have been more than 98% and 94%–99% as documented in the literature, respectively. Engagement of basal bicortical bone is done which is highly mineralized and least resistant to resorption for achieving good torque. Bicortical engagement of implants has proven to achieve better stabilization with less stresses on the crestal bone and implants."*
9	4.0 - 5.0 mm	20 - 25 mm; (K160119 Implants used in this study did not have a predicate with 22 & 25 mm Lengths per the 510(k) Summary)	15 - 45° drill protocol with 30° abutment	*"In this prospective cohort study, 18 patients (9 male and 7 female) with an average age of 62 years (age range: 33 to 82 years) with complete edentulous arches (n = 17). There were no implant failures, rendering a cumulative implant survival rate of 100%."* [at 24 months] *Several studies using the same implant design reported survival rates on the short-term outcome between 97.6% and 100%."*

EQUIVALENCE TO MARKETED DEVICE

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

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

	Subject Device	**Reference Device**
Comparison	Blue Sky Bio, LLC Blue Sky Bio Implant System	Southern Implants, Inc. Southern Implants PEEK Abutments K191250
Abutment	**PEEK Abutment**	
Indication for Use	Blue Sky Bio PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation
Abutment Design	Screw retained Internal Connection	Screw retained Engaging and Non-Engaging
Platform Diameter	3.5 mm, NP (3.5)	3.35 mm – 4.00 mm
Abutment Angle	Straight	Straight
Materials		
Abutments	Polyetheretherketone (PEEK)	Polyetheretherketone (PEEK)
Abutment Screws	NA	Ti-6Al-4V

	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Implant System	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K190958	Implant Direct Spectra Dental Implant System K061319	Southern Implants (Pty) Ltd. External Hex Implants K163634	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K190491 K153064	Nobel Biocare AB NobelSpeedy Groovy K160119	Blue Sky Bio, LLC Blue Sky Bio Dental Implant System K060957 K102034
Implants	**BIO|MAX MULTI ONE LONG**						
Indications for Use	Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants			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.		
Design	One-piece implant/abutment	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments, or one-piece implant/abutment	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments, or one-piece implant/abutment
Platform Ø, mm	3.5, NP (3.5)	3.75; 4.0	3.0, 3.5, 3.7, 4.3, 4.5,4.7 5.0, 5.7, 6.0, 6.5	3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	K153064 Internal hex connection: 4.7, Tapered internal hex connection: 4.3, 5.0	4.0	3.5, 4.3, 4.5 6.5
Implant Body Ø, mm	3.7 4.3, 5.0	3.75; 4.0	3.0, 3.5, 3.7, 4.3, 4.5,4.7, 5.0, 5.7, 6.0	3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	K153064 3.5, 4.1, 4.3, 4.7, 5.0	4.0	3.0 - 8.0
Implantable Length, mm	20, 22.5, 25	20; 22.5; 25	8, 10, 13, 16	6, 7, 8.5, 10, 11.5, 13, 15, 16, 18, 20	K153064 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55	20; 22.5; 25	6 - 16
Implant/Abutment Interface Type	One-piece	Morse taper	Internal hex External Hex Tri-Lobe; One Piece	External Hex	K153064 Internal hex with 12° taper Internal hex with 45° bevel	External Hex	Internal hex with 12° taper Internal hex with 45° bevel Square hex; One Piece
One-piece abutment angle	Straight, 17°, 30°, 45° (45° in pterygoid placement only)	NA	Straight, 12°	NA	NA	NA	Straight

Blue Sky Bio Dental Implant System

	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
Abutment Angle	NA	Straight, 17°, 30°	Straight, 15°, 30°	Straight, 12°, 17°, 24°, 30°	17°, 30°, 45°	NA	15°, 25°, 30°
Implant Surface	Grit blasted and acid etched	Acqua™ Hydrophilic Surface	HA RBM or HA Coated	Grit blasted and acid etched	Grit blasted and acid etched	TiUnite	Grit blasted and acid etched
Materials							
Implants	Ti-6Al-4V	F67 unalloyed titanium, Gr 4	Titanium Alloy	Unalloyed titanium	Ti-6Al-4V	CPTi	Ti-6Al-4V

	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Implant System	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K190958	Implant Direct Spectra Dental Implant System K061319	Southern Implants (Pty) Ltd. External Hex Implants K163634	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K190491 K153064	Nobel Biocare AB NobelSpeedy Groovy K160119	Blue Sky Bio, LLC Blue Sky Bio Dental Implant System K060957 K102034
Implants	**BIO|LONG Implants (**BIO|INTERNAL HEX LONG; BIO|MAX LONG)						
Indications for Use	Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants			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.		
Design	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments, or one-piece implant/abutment	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments, or one-piece implant/abutment
Platform Ø, mm	3.5, NP (3.5)	3.75; 4.0	3.0, 3.5, 3.7, 4.3, 4.5,4.7 5.0, 5.7, 6.0, 6.5	3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	K153064 Internal hex connection: 4.7, Tapered internal hex connection: 4.3, 5.0	4.0	3.5, 4.3, 4.5 6.5

Blue Sky Bio Dental Implant System

	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
Implant Body Ø, mm	3.7 4.3, 5.0	3.75; 4.0	3.0, 3.5, 3.7, 4.3, 4.5,4.7, 5.0, 5.7, 6.0	3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	K153064 3.5, 4.1, 4.3, 4.7, 5.0	4.0	3.0 - 8.0
Implantable Length, mm	20, 22.5, 25	20; 22.5; 25	8, 10, 13, 16	6, 7, 8.5, 10, 11.5, 13, 15, 16, 18, 20	K153064 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55	20; 22.5; 25	6 - 16
Implant/Abutment Interface Type	Internal hex with 12° taper Internal hex with 45° bevel	Morse taper	Internal hex External Hex Tri-Lobe; One Piece	External Hex	K153064 Internal hex with 12° taper Internal hex with 45° bevel	External Hex	Internal hex with 12° taper Internal hex with 45° bevel Square hex; One Piece
Abutment Angle	Straight, 12°, 17°, 24°, 30°, 45° (45° used with BIO|MAX LONG in pterygoid placement only)	Straight, 17°, 30°	Straight, 15°, 30°	Straight, 12°, 17°, 24°, 30°	17°, 30°, 45°	NA	15°, 25°, 30°
Implant Surface	Grit blasted and acid etched	Acqua™ Hydrophilic Surface	HA RBM or HA Coated	Grit blasted and acid etched	Grit blasted and acid etched	TiUnite	Grit blasted and acid etched
Materials							
Implants	Ti-6Al-4V	F67 unalloyed titanium, Gr 4	Titanium Alloy	Unalloyed titanium	Ti-6Al-4V	CPTi	Ti-6Al-4V

	Subject Device	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Implant System	Implant Direct Spectra Dental Implant System K061319	Southern Implants (Pty) Ltd. External Hex Implants K163634	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K190491 K153064	Blue Sky Bio, LLC Blue Sky Bio Dental Implant System K060957 K102034	Zimmer Dental, Inc. Zimmer One-Piece Implant, 3.0mm, Angled K071235
Implants	**BIO|MAX MULTI ONE**					
Indication	Blue Sky Bio Multi One Implant System is intended for surgical placement in the bone of the upper or lower jaw to provide support for prosthetic devices to restore chewing function. Implants may be used with single-stage or two-stage procedures. They can be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Multi One Implants are indicated for multi-unit restorations in splinted applications. Blue Sky Bio Multi One Implant System with a 45° angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.	The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage or two¬ stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established. The ScrewDirect 3.0 mm implant is indicated for: 1.An artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. 2.Multiple tooth replacements or denture stabilization.		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.		
Design	One-piece implant/abutment	Threaded root-form implant to be used with mating abutments, or one-piece implant/abutment	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments, or one-piece implant/abutment	Threaded root-form implant with one-piece implant/abutment design

Blue Sky Bio Dental Implant System

	Subject Device	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
Platform Ø, mm	3.5, NP (3.5)	3.0, 3.5, 3.7, 4.3, 4.5, 4.7, 5.0, 5.7, 6.0, 6.5	3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	K153064 Internal hex connection: 4.7, Tapered internal hex connection: 4.3, 5.0	3.5, 4.3, 4.5 and 6.5	NA
Implant Body Ø, mm	3.0, 3.25, 3.5, 3.7 4.3	3.0, 3.5, 3.7, 4.3, 4.5, 4.7, 5.0 5.7, 6.0	3.25, 3.75, 4.0, 4.7, 5.0, 5.7 and 6.0	K153064 3.5, 4.1, 4.3, 4.7, 5.0	3.0 mm to 8.0	3.0
Implantable Length, mm	10, 11.5, 13, 16, 18, 20	8, 10, 13, 16	6, 7, 8.5, 10, 11.5, 13, 15, 16, 18, 20	K153064: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55	6 to 16	10, 11.5, 13, 16
Implant/Abutment Interface Type	One Piece	Internal hex External Hex Tri-Lobe; One Piece	External Hex	K153064 Internal hex with 12° taper Internal hex with 45° bevel	Internal hex with 12° taper Internal hex with 45° bevel Square hex; One Piece	One-Piece
One-piece abutment angle	Straight, 17°, 30°, 45°	Straight, 12°	NA	NA	Straight	17°
Abutment Angle	NA	Straight, 15°, 30°	Straight, 12°, 17°, 24°, 30°	17°, 30°, 45°	15°, 25°, 30°	NA
Implant Surface	Grit blasted and acid etched	HA RBM or HA Coated	Grit blasted and acid etched	Grit blasted and acid etched	Grit blasted and acid etched	MTX – HA RBM
Materials						
Implants	Ti-6Al-4V	Titanium Alloy	Unalloyed titanium	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V

DISCUSSION:

The indications for use for the primary predicate K190958 do not include pterygoid placement and do not contain language to state that the implants with 45° angulation are indicated for the pterygoid region only. Thus, the indications for use for the subject device was updated to be in line with the K190491 indications for use which contain language specific to zygomatic placement and supported by clinical data.

The subject device sizes for implants Ø3.5 – Ø5.0 mm with lengths of 10 mm – 25 mm do not raise new questions of safety and effectiveness compared to the predicate devices and the clinical literature. BIO|MAX MULTI ONE Implants, Blue Sky Bio BIO|LONG implants, and BIO|MAX MULTI ONE LONG implants are provided in lengths of 10-25 mm and placed at an angle of 45° or less. This is within the window of the successful implants identified in the literature and the predicate devices. They are shorter than the lengths placed in the zygoma which have less bone to implant contact and greater fulcrum force. Therefore, BIO|MAX MULTI ONE Implants, Blue Sky Bio BIO|LONG implants and BIO|MAX MULTI ONE LONG implants do not present greater risk than zygomatic implants.

CONCLUSION

The subject device and the predicate devices have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading. The implants of the subject device and the predicate devices have similar designs and dimensions, including lengths appropriate for pterygoid placement supported by the referenced literature.

The subject device implants and abutments have similar packaging and are sterilized using the same materials and processes as the sponsor’s own predicate devices.

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