December 18, 2020

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

Re: K202026
Trade/Device Name: Blue Sky Bio CAD-CAM Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 17, 2020
Received: December 18, 2020

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,

Andrew Steen
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K202026

Device Name

Blue Sky Bio CAD-CAM Abutments

Indications for Use *(Describe)*

Blue Sky Bio CAD-CAM Abutments are intended to be used in conjunction with Blue Sky Bio endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed abutments for use with Blue Sky Bio CAD-CAM Abutments are intended to be sent to a Blue Sky Bio validated milling center for manufacture.

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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# 510(k) Summary
# K202026
# Blue Sky Bio, LLC
# Blue Sky Bio CAD-CAM Abutments

December 17, 2020

ADMINISTRATIVE INFORMATION

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

DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name | Blue Sky Bio CAD-CAM Abutments |
| Common Name | Endosseous dental implant abutment |
| Classification Regulations | 21 CFR 872.3630 |
| Regulation Name | Endosseous dental implant abutment |
| Regulatory Class | Class II |
| Product Code | NHA |
| Classification Panel | Dental |
| Reviewing Office | Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices) |
| Reviewing Division | Division of Health Technology 1B (Dental Devices) |

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K191986, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K180536, Neodent Implant System - GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K051507, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K183518, Preat Abutments, Preat Corporation
K151984, Milling Abutment For CAD/CAM, Thommen Medical AG

## INDICATIONS FOR USE STATEMENT

Blue Sky Bio CAD-CAM Abutments are intended to be used in conjunction with Blue Sky Bio endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed abutments for use with Blue Sky Bio CAD-CAM Abutments are intended to be sent to a Blue Sky Bio validated milling center for manufacture.

## SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for Blue Sky Bio CAD-CAM Abutments, to be used with compatible components from the Blue Sky Bio Dental Implant System cleared in K051507, K060957, and K102034. The subject device includes Titanium Base Abutments, Cobalt Base Abutments, and Titanium Blank Abutments.

For the Titanium Base Abutments and the Cobalt Base Abutments, the final finished device is intended to be used as a two-piece abutment composed of the base bottom-half (titanium base or cobalt base) bonded to a CAD-CAM zirconia top-half.

Each abutment type provided in six (6) internal implant connections to the previously-cleared compatible Blue Sky Bio implants (BIO | MAX; BIO | Internal Hex; BIO | Quattro; BIO | Conus 12; BIO | One Stage; and BIO | Trilobe).

Titanium Base Abutments are designed for retention of a CAD-CAM fabricated zirconia superstructure and are provided in both straight and 15° angled base designs, and with engaging, non-engaging, and non-engaging conical implant connections. The design parameters for the CAD-CAM zirconia superstructure for the Titanium Base Abutments are:

- Minimum wall thickness – 0.5 mm
- Minimum post height for single-unit restorations – 4.0 mm
- Minimum gingival height – 0.5 mm
- Maximum gingival height – 6.70 mm
- Maximum angulation
  - Straight Titanium Bases – superstructure maximum angle – 30°
  - Angled Titanium Bases – superstructure maximum angle – 15°
  - The maximum angulation of the final abutment – 30°

Cobalt Base Abutments are provided in both straight and 15° angled base designs, and with engaging and non-engaging implant connections. Cobalt Base Abutments (Straight) are designed to be a base for a final abutment fabricated by either of two methods. The first method is the same as for the Titanium Base Abutments: a CAD-CAM fabricated zirconia superstructure is bonded to the Cobalt Base Abutment (Straight) and the final two-piece abutment is used for the prosthetic restoration. The maximum angulation of the final abutment is up to 30°.For the second method, the Cobalt Base Abutments

(Straight) can be cast to a straight abutment only, no angulation. The design of the final abutment can be by CAD-CAM, fabricated in wax, and fixed to the Cobalt Base Abutment, or the final design be done using traditional wax-up technique. The final one-piece abutment is fabricated using standard lost wax casting techniques.

Cobalt Base Abutments (Angled 15°) are designed to be a base for a CAD-CAM fabricated zirconia superstructure bonded to the Cobalt Base Abutment (Angled 15°) and the final two-piece abutment is used for the prosthetic restoration. The maximum angulation of the coping for the Cobalt Base Abutments (Angled 15°) is up to15°; the final abutment will have an angulation of up to 30°.
Cobalt Base Abutments (Angled 15°) are not to be cast to a final abutment.

The design parameters for the CAD-CAM zirconia superstructure for the Cobalt Base Abutments are:
- Minimum wall thickness – 0.5 mm
- Minimum post height for single-unit restorations – 4.0 mm
- Minimum gingival height – 0.5 mm
- Maximum gingival height – 6.7 mm
- Maximum angulation
  - Cobalt Base Abutments (Straight) – superstructure maximum angle – 30°
  - Cobalt Base Abutments (Angled 15°) – superstructure maximum angle – 15°
  - The maximum angulation of the final abutment – 30°

For Cobalt Base Abutments (Straight) that are finalized to a one-piece abutment by lost wax casting, the design parameters are:
- Minimum wall thickness – 0.5 mm;
- Minimum post height for single-unit restorations – 4.0 mm
- Minimum gingival height – 0.5 mm
- Maximum gingival height – 6.7 mm
  - Maximum angulation – 0°, straight final abutment only

Titanium Blank Abutments are designed for fabrication of a customized all titanium alloy abutment by CAD-CAM processes. Titanium Blank Abutments have an engaging implant connection.
The design parameters for customized abutments fabricated from Titanium Blank Abutments are:
- Minimum wall thickness – 0.4 mm
- Minimum post height for single-unit restorations – 4.0 mm
- Minimum gingival height – 0.5 mm
- Maximum gingival height – 6.7 mm
- Maximum angulation – 30°

The subject device abutments are made of titanium alloy conforming to ASTM F136 , or cobalt-chromium alloy conforming to ASTM F1537. The titanium alloy subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Blue Sky Bio products cleared previously in K051507, K060957, and K102034.

All zirconia superstructures (copings) for use with the subject devices Titanium Base Abutments and Cobalt Base Abutments will be made at a Blue Sky Bio validated milling center under FDA quality system regulations, and the material will conform to ISO 13356. All wax designs for casting to the subject device Cobalt Base Abutments also will be made at a Blue Sky Bio validated milling center. For the lost wax technique, final one piece abutment may be cast in cobalt-chromium alloy or nickel-chromium alloy.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 17665-2 (referenced from Blue Sky Bio submissions K073713 and K153064); biocompatibility testing according to ISO 10993-5 and ISO 10993-12; and static and dynamic compression-bending testing according to ISO 14801. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The primary predicate device K191986 is for support of substantial equivalence of the Indications for Use statement and for the use of the Co-Cr alloy material. The reference device K180536 is for support of substantial equivalence of the CAD-CAM abutment designs. The reference devices K102034, K060957, and K051507 are for support of substantial equivalence of the identical Blue Sky Bio dental implant interface connections and platforms. The reference device K183518 is for support of substantial equivalence of the performance testing data. The reference device K151984 is for support of substantial equivalence of the subject device maximum gingival height of 6.7 mm.

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. All are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. 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 devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the to the primary predicate device and the reference devices listed above; differences in language of the Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

Similarities between the IFUS for the subject device and the primary predicate K191986 include wording regarding support for maxillary or mandibular prosthetic restorations and the requirement for use validated milling centers. The minor differences between the IFUS for the subject device and the primary predicate K191986 include specific device names and wording regarding dental implant compatibilities in the IFUS for K191986.

The minor differences between the IFUS for the subject device and the reference device K180536 include wording regarding dental implants (not applicable to the subject device), and wording about the specific abutment designs in K180536. Similarities between the IFUS for the subject device and the reference device K180536 include wording regarding single-unit and multi-unit restorations and the requirement for use validated milling centers.

The reference devices K102034, K060957, and K051507 are for substantial equivalence of the identical Blue Sky Bio dental implant interface connections and platforms, the reference device K183518 is for

support of substantial equivalence of the performance testing data, and the reference device K151984 is for support of substantial equivalence of the subject device maximum gingival height of 6.7 mm. Differences among the IFUS for the subject device and these reference devices are wording regarding the implant components included in K102034, K060957, K051507, and K151984; the relevant similarities include wording concerning prosthetic support of single-unit and multi-unit restorations. Similarities between the IFUS for the subject device and K183518 include wording on the intended use for and single-unit and multi-unit restorations and the requirement for use validated milling centers. Minor differences between the IFUS for the subject device and K183518 include specific wording about base abutments and the listing of compatible implant systems. None of these minor differences impact substantial equivalence because all IFUS express an equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The subject device abutments have interface connections and platforms that are identical to the compatible Blue Sky Bio dental implants cleared in the reference devices K102034, K060957, and K051507. The subject device includes designs for compatible Blue Sky Bio implant platforms ranging from 2.8 mm (Mini) to 4.5/5.0 mm.

The subject device Titanium Base Abutments, Cobalt Base Abutments, and Titanium Blank Abutments designs are substantially equivalent in material, design, and ranges of sizes to the corresponding abutments in K180536, K191986, K183518, and K151984. The maximum gingival height for the subject device abutments is 6.7 mm, which is substantially equivalent to the gingival height of the CAD-CAM abutments cleared in K151984.

Minor differences in the design parameters for zirconia copings to be used with the subject device base abutments and the predicate device base abutments (minimum wall thickness, maximum gingival height, maximum angulation) are mitigated by mechanical testing performed in conformance with ISO 14801. Similarly, minor differences in the design parameters for the subject device blank abutments and the predicate device blank abutments also are mitigated by mechanical testing performed in conformance with ISO 14801.

The subject device includes abutments made of titanium alloy conforming to ASTM F136. The titanium alloy subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Blue Sky Bio products cleared previously in the reference devices K051507, K060957, and K102034. In addition, subject device titanium alloy abutments are anodized in various colors for ease of identification of the abutment platform. This anodization process is identical to the anodization process used on Blue Sky Bio abutments cleared in the reference device K102034.

The subject device also includes abutments made of cobalt-chromium alloy conforming to ASTM F1537. Substantial equivalence for the subject device Cobalt Base abutments is supported by use of the same material for abutments in the primary predicate device K191986. The subject device Titanium Base Abutments and Cobalt Base Abutments are to be used with copings fabricated from zirconia conforming to ISO 13356. This is the same material used for copings in the primary predicate device K191986.

Confirmatory biocompatibility testing for the subject device cobalt-chromium alloy and zirconia materials was performed according to ISO 10993-5 and ISO 10993-12.

Mechanical performance testing of the subject device was performed in conformance to ISO 14801. The fatigue limit data demonstrated that constructs of the subject device abutments, fabricated to the limits stated in the proposed labeling, in combination with previously-cleared compatible Blue Sky Bio implants have sufficient strength for their intended use.

Minor differences in the designs, dimensions, sizes, or compatible implant lines among the subject device, the primary predicate device, and the reference devices do not affect substantial equivalence. These minor differences do not impact safety or effectiveness because these differences are related to the compatible implant designs and are mitigated by the mechanical performance testing.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, and the reference devices 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 –Indications for Use Statement

| Subject Device | Primary Predicate Device | Reference Device | Reference Device | Reference Device | Reference Device | Reference Device | Reference Device |
|---|---|---|---|---|---|---|---|
| **K202026**<br>**Blue Sky Bio CAD-CAM Abutments**<br>**Blue Sky Bio, LLC** | **K191986**<br>**DESS Dental Smart Solutions**<br>**Terrats Medical SL** | **K180536**<br>**Neodent Implant System – GM Line**<br>**JJGC Indústria e Comércio de Materiais Dentários S.A.** | **K191986**<br>**DESS Dental Smart Solutions**<br>**Terrats Medical SL** | **K102034**<br>**Blue Sky Bio Dental Implant System**<br>**Blue Sky Bio, LLC** | **K060957**<br>**Blue Sky Bio Dental Implant System**<br>**Blue Sky Bio, LLC** | **K051507**<br>**Blue Sky Bio Dental Implant System**<br>**Blue Sky Bio, LLC** | **K183518**<br>**Preat Abutments**<br>**Preat Corporation** |
| Blue Sky Bio CAD-CAM Abutments are intended to be used in conjunction with Blue Sky Bio endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.<br><br>All digitally designed abutments for use with Blue Sky Bio CAD-CAM Abutments are intended to be sent to a Blue Sky Bio validated milling center for manufacture. | DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.<br>All digitally designed custom abutments for use with Ti Base abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture.<br><br>*For table of Compatible Implant Systems see complete K191986 predicate literature in this section.* | Indications for Use for GM Helix Implants and conventional abutments:<br>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.<br><br>Indications for Use for GM Exact Titanium Block for Medentika Holder:<br>GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.<br><br>Indications for Use for GM Exact Titanium Base abutments:<br>Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.<br><br>Indications for Use for Titanium Base C for GM Exact abutments:<br>The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations.<br>All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. | DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.<br>All digitally designed custom abutments for use with Ti Base abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture.<br><br>*For table of Compatible Implant Systems see complete K191986 predicate literature in this section.* | Intended Use for Two-Piece Implant Systems<br>• For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For single tooth or multiple unit prosthesis<br>• For single stage or two stage surgical procedure<br>• For immediate placement and immediate function when multiple units are splinted and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. Multiple units may be splinted with a bar. In edentulous cases restored with a fixed prosthesis, four or more implants must be used.<br>• Unsplinted narrow implants and angled abutments are not to be used in the posterior areas.<br>• Taper Hex Implant System is compatible with NobelActive implants and prosthetics<br>• Double Hex Implant System is compatible with Astra double hex implants and prosthetics<br>• Square Taper Implant System is compatible with Straumann Bone-Level implants and Prosthetics<br><br>Intended Use for One-Piece Implant System<br>• For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For single tooth or multiple unit prosthesis<br>• For single stage surgical procedure<br>• For immediate placement and immediate function when multiple units are splinted and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. In edentulous cases four or more implants must be used<br>• Overdenture Implants are intended for support of removable prosthesis. | Indications for Use:<br>• For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For implantation into any area of the partially edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For single tooth or multiple unit prosthesis<br>• For single stage or two stage surgical procedure<br>• One piece implants for single stage procedure only<br>• For immediate placement and immediate function when multiple units are splinted and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. Multiple units may be splinted with a bar. In edentulous cases restored with a fixed prosthesis, four or more implants must be used. | Indications for Use:<br>• For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For implantation into any area of the partially edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis<br>• For single tooth or multiple unit prosthesis<br>• For single stage or two stage surgical procedure<br>• One piece implants for single stage procedure only<br>• For immediate placement and immediate function when multiple units are splinted and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. Multiple units may be splinted with a bar. In edentulous cases restored with a fixed prosthesis, four or more implants must be used. | Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.<br><br>All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.<br><br>*For table of Compatible Implant Systems see complete K183518 predicate literature in this section.* |

## Table of Substantial Equivalence – Technological Characteristics

| | **Subject Device** | **Primary Predicate Device** | **Reference Device** | **Reference Device** | **Reference Device** | **Reference Device** | **Reference Device** |
|---|---|---|---|---|---|---|---|
| | **K202026<br>Blue Sky Bio CAD-CAM Abutments<br>Blue Sky Bio, LLC** | **K191986<br>DESS Dental Smart Solutions<br><br>Terrats Medical SL** | **K180536<br>Neodent Implant System – GM Line<br>JJGC Indústria e Comércio de Materiais Dentários S.A.** | **K102034<br>Blue Sky Bio Dental Implant System<br>Blue Sky Bio, LLC** | **K060957<br>Blue Sky Bio Dental Implant System<br>Blue Sky Bio, LLC** | **K051507<br>Blue Sky Bio Dental Implant System<br>Blue Sky Bio, LLC** | **K183518<br>Preat Abutments<br><br>Preat Corporation** |
| **Reason for Primary Predicate / Reference Device** | **Not applicable** | **Indications for Use Statement<br>Co-Cr Base material** | **CAD-CAM abutment designs** | **Compatible identical implant interface and platforms** | **Compatible identical implant interface and platforms** | **Compatible identical implant interface and platforms** | **Performance testing data** |
| **Product Codes** | NHA | NHA | DZE, NHA | DZE, NHA | DZE | DZE | NHA |
| **Intended Use** | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla |
| **Designs/Features** | | | | | | | |
| Abutment Design | Titanium Base Abutments<br>Cobalt Base Abutments<br>Titanium Blank Abutments | Ti Base<br>CrCo Base<br>Pre-milled (Blank) Abutments | Titanium Base Abutments<br>Titanium Block Abutments (Blanks) | Conventional one-piece abutments | Conventional one-piece abutments | Conventional one-piece abutments | Various designs including:<br>Titanium Base Abutments<br>Titanium Blank Abutments |
| Restoration | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit |
| Prosthesis Attachment | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained |
| Abutment-Implant Interface | Internal | Internal | Internal | Internal | Internal | Internal | Internal |
| Abutment-Implant Platform Diameter (mm) | Mini (2.8)<br>NP (2.8)<br>RP (3.3)<br>3.5<br>3.5/4.0<br>4.5/5.0 | 2.52 – 6.5 | Not applicable<br>(Neodent GM line, Morse taper internal connection) | Mini (2.8)<br>NP (2.8)<br>RP (3.3)<br>3.5<br>3.5/4.0<br>4.5/5.0 | | | 3.0 – 6.5 |
| | 3.5<br>4.3<br>4.5<br>5.0 | | | | 3.5<br>4.3<br>4.5<br>5.0 | | |
| | NP (3.5)<br>RP (3.5)<br>WP (4.3) | | | | | NP (3.5)<br>RP (3.5)<br>WP (4.3) | |
| Prosthetic Platform Diameter | 3.9 mm – 6.5 mm | 4.5 mm – 6.5 mm | 4.65 mm, 5.5 mm | | | | *Not stated in 510(k) Summary* |
| Base Abutments – Coping Design Parameters | | | | | | | |
| Minimum wall thickness | 0.5 mm | 0.4 mm | *Not stated in 510(k) Summary* | | | | 0.5 mm |
| Minimum post height | 4.0 mm | 4.2 mm | 4 mm | | | | 4.0 mm |
| Minimum gingival height (of the coping) | 0.5 mm | *Not stated in 510(k) Summary* | *Not stated in 510(k) Summary* | | | | *Not stated in 510(k) Summary* |
| Maximum gingival height (of the coping) | 6.7 mm | 6.0 mm | *Not stated in 510(k) Summary* | | | | 5.0 mm |
| Angulation of Finished Abutment | Up to 30° | 0° (straight only) | 20°, 30° | | | | 0° (straight only) |
| Cement to bond coping to base | Multilink Hybrid Abutment Cement,<br>(Ivoclar Vivadent AG) | *Not stated in 510(k) Summary* | *Not stated in 510(k) Summary* | | | | *Not stated in 510(k) Summary* |
| Blank Abutments – Final Design Parameters | | | | | | | |
| Minimum wall thickness | 0.4 mm | 0.4 mm | *Not stated in 510(k) Summary* | | | | 0.5 mm |
| Minimum post height | 4 mm | 4 mm | *Not stated in 510(k) Summary* | | | | 4.0 mm |
| Minimum gingival height | 0.5 mm | *Not stated in 510(k) Summary* | *Not stated in 510(k) Summary* | | | | *Not stated in 510(k) Summary* |
| Maximum gingival height | 6.7 mm | 6.0 mm | *Not stated in 510(k) Summary* | | | | 1.5 – 2.65 (varies by implant line) |
| Angulation of Finished Abutment | Up to 30° | 0° (straight only) | Up to 30° | | | | Up to 30° |

| | **Subject Device** | **Primary Predicate Device** | **Reference Device** | **Reference Device** | **Reference Device** | **Reference Device** | **Reference Device** |
|---|---|---|---|---|---|---|---|
| | **K202026**<br>**Blue Sky Bio CAD-CAM Abutments**<br>**Blue Sky Bio, LLC** | **K191986**<br>**DESS Dental Smart Solutions**<br><br>**Terrats Medical SL** | **K180536**<br>**Neodent Implant System – GM Line**<br>**JJGC Indústria e Comércio de Materiais Dentários S.A.** | **K102034**<br>**Blue Sky Bio Dental Implant System**<br>**Blue Sky Bio, LLC** | **K060957**<br>**Blue Sky Bio Dental Implant System**<br>**Blue Sky Bio, LLC** | **K051507**<br>**Blue Sky Bio Dental Implant System**<br>**Blue Sky Bio, LLC** | **K183518**<br>**Preat Abutments**<br><br>**Preat Corporation** |
| **Materials** | | | | | | | |
| Abutment Materials | Titanium alloy, ASTM F136<br>Cobalt-chromium alloy, ASTM F1537<br>Copings:<br>Zirconia, ISO 13356 | Titanium alloy, ASTM F136<br>Cobalt-chromium alloy, ASTM F1537<br>Copings:<br>Zirconia, ISO 13356 | Titanium alloy, ASTM F136<br><br>*Materials for copings not stated in 510(k) Summary* | Titanium alloy, ASTM F136<br><br>*Materials for copings not applicable* | Titanium alloy, ASTM F136<br><br>*Materials for copings not applicable* | Titanium alloy, ASTM F136<br><br>*Materials for copings not applicable* | Titanium alloy, ASTM F136<br><br>Copings:<br>Zirconia, ISO 13356 |