June 03, 2026

SIC invent AG
% Kevin Thomas
VP and Director of Regulatory Affairs
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

Re: K252904
Trade/Device Name: SIC Abutments including CAD/CAM Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 30, 2026
Received: May 1, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252904

Please provide the device trade name(s).

SIC Abutments including CAD/CAM Solutions

Please provide your Indications for Use below.

SIC CAD/CAM Products are intended for use with SIC Dental Implants for prosthetic restorations from single tooth replacements to full arch restorations with fixed or removable superstructures.
The Bonding Bases consist of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Bonding Base or Milling Blank are to be sent to an SIC invent validated milling center for manufacture.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K252904
SIC invent AG
SIC Abutments including CAD/CAM Solutions

June 2, 2026

ADMINISTRATIVE INFORMATION

Manufacturer Name	SIC invent AG Birmannsgasse 3 Basel, CH-4055, Switzerland Telephone +41 61 260 24 60
Official Contact	Marcus von Malottki, Chief Technology Officer
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA Rebecca E. Kattan, PhD PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone +1 858-792-1235 Email kthomas@paxmed.com flarosn@paxmed.com rkattan@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	SIC Abutments including CAD/CAM Solutions
Common Name	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K173207, SIC invent Dental Implant Systems, SIC invent AG

Reference Devices
K210489, SICtapered & SICvantage tapered, SIC Invent AG
K240208, DESS Dental Smart Solutions, Terrats Medical SL
K233316, DESS Dental Smart Solutions, Terrats Medical SL
K202026, Blue Sky Bio CAD-CAM Abutments, Blue Sky Bio, LLC
K193096, S.I.N. Dental Implant System, S.I.N. – Sistema de Implante Nacional S.A.
K211109, N1™ TiUltra™ TCC Implant System, Nobel Biocare Services AG

The primary predicate device is K173207, and is for support of substantial equivalence in terms of abutment material, manufacturing, biocompatibility, sterilization, and compatible implant designs (SICace®, SICmax®, and SICtapered implants with an internal hex connection; and SICvantage® max, SICvantage® tapered implants with internal taper connection). The reference device K210489 is for additional compatible implant designs (SICtapered implants with an internal hex connection; and SICvantage® tapered implants with an internal taper connection). The reference devices K240208, K233316, K202026, K193096, and K211109 are for support of substantial equivalence in terms of various abutment designs.

INDICATIONS FOR USE STATEMENT

SIC CAD/CAM Products are intended for use with SIC Dental Implants for prosthetic restorations from single tooth replacements to full arch restorations with fixed or removable superstructures. The Bonding Bases consist of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Bonding Base or Milling Blank are to be sent to an SIC invent validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

SIC Bonding Bases (Ti Base abutments) are two-piece abutments composed of a CAD/CAM fabricated zirconia superstructure and a prefabricated titanium alloy base component where the final two-piece abutment (base and cemented superstructure) is the finished device used for the prosthetic restoration. SIC Bonding Bases are provided in engaging and non-engaging designs for single-unit and multi-unit restorations, respectively.

The subject SIC Bonding Bases are provided with a gingival height (in the prefabricated titanium base) ranging from 0.3 mm to 3 mm, and a prosthetic platform diameter ranging from 3.3 mm to 4.5 mm. Additional gingival height may be provided in the zirconia superstructure. The subject SIC Bonding Base CAD/CAM abutments (for SIC implants with an internal hex connection) are provided in both straight and 15° angled designs. The subject Ti Base Abutments for SIC invent implants with an internal taper connection (SICvantage Bonding Base CAD/CAM) are provided only in a straight design. Additional angulation may be provided in the zirconia superstructure only for the Ti Base Abutments for SIC invent implants with an internal hex connection; the Ti Base Abutments for the implants with an internal taper connection are only for fabrication of a straight final abutment. The prefabricated bases have prosthetic post heights ranging from 4 mm to 4.9 mm for bases with a uniform post height, and a post height of 6 mm (maximum) for bases with a cut-down post to accommodate angled access to the screw channel. The cementable post height (measured above the combined gingival collar) may not be less than 4 mm for a single-unit restoration.

The design parameters for the CAD/CAM zirconia superstructure to be used on the SIC Bonding Base CAD/CAM abutments and SICvantage Bonding Base CAD/CAM abutments are:

Minimum wall thickness – 0.5 mm

Minimum abutment post height for single-unit restoration – 4.0 mm
(Abutment post height is the height above the gingival height)

Minimum gingival height – 0.3 mm

Maximum gingival height – 4.0 mm

Maximum angulation for SIC Bonding Base CAD/CAM
(for SICace®, SICmax®, SICtapered implants)
Angled Titanium Bases – superstructure maximum angle – 15°
Straight Titanium Bases – superstructure maximum angle – 30°
The maximum angulation of the final abutment – 30°

Maximum angulation for SICvantage Bonding Base CAD/CAM
(for SICvantage® max, SICvantage® tapered implants) – 0°
The final abutment is straight only, no angulation.

The subject SIC Bonding Bases are manufactured by SIC invent, including the implant-abutment interface. Fabrication of the patient-specific zirconia superstructure will be performed at an SIC invent validated milling center under FDA quality system regulations. The material for the superstructure will conform to ISO 13356. The required cement for bonding of the zirconia superstructure to the abutment base is 3M ESPE RelyX Unicem bonding cement (cleared in K022476).

SIC Milling Blanks (Pre-Milled Blank Abutments) are cylindrical titanium alloy abutments designed for patient-specific abutment fabrication by a CAD/CAM process and machined into a one-piece, all titanium abutment. The portion of the abutment available for milling is either 10, 11.5, or 12 mm in diameter. All SIC Milling Blanks have an engaging connection. The maximum prosthetic platform diameter is based on the clinically available interproximal space. SIC Milling Blanks are provided in five (5) designs, each in three (3) variations for attachment to the mailing machine holders (A-Line for ARUM Dentistry, M-Line for Medentika PreFace, and AG-Line for Amann Girrbach).

The design parameters for the CAD/CAM Pre-Milled Blank custom abutments are:

Minimum wall thickness – 0.5 mm
Minimum abutment post height – 4.0 mm
(Abutment post height is the height above the gingival height)
Minimum gingival height (for SICace®, SICmax®, SICtapered implants) – 0.3 mm
Minimum gingival height (for SICvantage® max, SICvantage® Tapered implants) – 0.5 mm
Maximum gingival height – 3.0 mm
Maximum Angulation – 30°

The subject Pre-Milled Blank Abutments are manufactured by SIC invent, including the implant-abutment interface. The fabrication of the patient-specific final abutment will be performed at an SIC invent validated milling center under FDA quality system regulations. The implant-abutment interface portion of the abutment is not to be altered by the validated milling center.

SIC Multi-Unit Abutments are provided in a straight design (no angulation in the base portion) that threads directly to the compatible SICace®, SICmax®, or SICtapered implant. All subject SIC Mini Multi-Unit abutments have a maximum (prosthetic platform) diameter of 3.75 mm and are provided with gingival heights of 1.5 mm or 3.0 mm. The SIC Mini Multi-Unit abutments require an abutment level component metal coping to attach to the multi-unit abutment. This submission includes one (1) new SIC Mini Multi-Unit Crown Base, for fabrication of a restoration using conventional laboratory workflow or a CAD/CAM workflow. The subject SIC Mini Multi-Unit Crown Base has a maximum (prosthetic platform) diameter of 4 mm, a gingival height of 0.25 mm, and a prosthetic post height of 5.65 mm. The prosthetic post height may be shortened to a minimum of 4 mm for a single-unit restoration. The SIC Mini Multi-Unit Crown Base is to be used straight only, with no angulation in the crown base.

SIC Provisional Abutments are designed to support temporary crowns which can be cemented or directly polymerized onto the abutment. The subject SIC Provisional Abutments are for use with previously cleared SICace®, SICmax®, or SICtapered implants, and have a prosthetic platform diameter of 3.6 mm or 4.5 mm, a gingival height of 0.5 mm, and a prosthetic post height of 12.3 mm. The post height can be shortened as needed to avoid occlusal interference; the minimum post height for a single-unit restoration is 4 mm.

All subject device components are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and ISO 5832-3. Selected subject device components are color-coded by anodization using the same process to anodize components cleared in K210489. The subject device abutments are used with previously cleared SIC invent screws or subject device screws included in this submission.

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included the following:

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods,

J.G. Delfino, and S. Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation Volume 49, No. 2 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition; the 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;

- referenced from K173207 was moist heat sterilization for the subject device conventional abutments (not CAD/CAM) and prosthetic components provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2;
- provided in this submission was moist heat sterilization validation for the subject CAD/CAM devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2;
- referenced from K173207 was biocompatibility testing according to ISO 10993-5 and ISO 1003-12, applicable to the subject device all-titanium abutments manufactured from ASTM F136 alloy, including SIC Milling Blanks (Pre-Milled Blank Abutments), SIC Multi-Unit Abutments, SIC Provisional Abutments, and fixation screws;
- provided in this submission was biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the subject Bonding Base material with the required zirconia (NexxZr, Sagemax Bioceramics, Inc., cleared in K062695) and the required cement (3M ESPE RelyX Unicem bonding cement, cleared in K022476);
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments in conjunction with the compatible SIC invent implants.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

Intended Use

The subject device abutments are substantially equivalent in intended use to the abutments cleared in primary predicate device K173207 and the reference devices K240208, K233316, K202026, K193096, and K211109. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation. The Indications for Use Statement (IFUS) for the subject device includes language requiring a validated milling center for manufacture of the custom abutments that is similar to language in the IFUS for the reference devices K240208 and K202026. The IFUS for the primary predicate K173207 and the reference device K210489 include additional details regarding dental implants that are not applicable to the subject device and do not change the intended use to provide functional and esthetic rehabilitation of the mandible and maxilla. The minor differences in the IFUS for the subject device, primary predicate device, and reference devices do not change the intended use, do not raise different questions of safety or effectiveness, and do not impact substantial equivalence.

Design, Materials and Technological Characteristics

With the exception of the SIC Bonding Bases (Ti Base abutments) and SIC Milling Blanks (Pre-Milled Blank Abutments), the subject device components (multi-unit abutments, provisional abutments, and abutments screws) are manufactured from identical materials, in the identical facilities, using the identical manufacturing processes as SIC Invent AG abutments and abutment screws previously cleared in the primary predicate device K173207. The SIC Bonding Bases and SIC Milling Blanks are customized to a final abutment at a validated milling center, and the SIC Bonding Bases require a zirconia top-half (NexxZr, Sagemax Bioceramics, Inc., cleared in K062695) bonded with the required cement (3M ESPE RelyX Unicem bonding cement, cleared in K022476).

The subject device SIC Bonding Bases (Ti Base) abutments have identical implant-abutment platform/connections to those of the compatible implants in the primary predicate device K173207 and the reference device K210489. The subject device titanium base abutments and the titanium base abutments in the reference devices K240208 and K202026 have similar or identical ranges of prosthetic platform diameter, gingival height, and coping design

parameters. The subject titanium base abutments with angulation in the base are substantially equivalent to angled based in the reference device K202026.

The subject device SIC Milling Blanks (pre-milled blank abutments) and pre-milled blank abutments in the reference devices K240208 and K202026 have similar or identical ranges of prosthetic platform diameter, gingival height, and final milled parameters.

The subject device multi-unit abutments and the multi-unit abutments in the primary predicate device K173207 and the reference devices K240208 and K233316 have similar or identical ranges of prosthetic platform diameter, gingival height, and angulation. The reference device K193096 includes multi-unit abutments with a prosthetic platform diameter of 3.5 mm, and is in support of substantial equivalence of the prosthetic platform diameter of the subject multi-unit abutments (3.75 mm).

The subject device temporary abutments and the temporary abutments in the reference devices K240208 and K233316 have similar or identical ranges of implant-abutment platform diameters, prosthetic platform diameter, gingival height, and angulation. The reference device K211109 includes temporary abutments with a prosthetic platform diameters of 3.4-4.5 mm, and is in support of substantial equivalence of the prosthetic platform diameter of the subject temporary abutments (3.6 mm and 4.5 mm).

The subject abutment screws are similar in design, materials, and technological characteristics to those cleared in the primary predicate device K173207.

The subject device components are provided non-sterile and are to be sterilized by the same moist heat cycle as the primary predicate device K173207. The subject devices are provided in pouches manufactured from a low-density polyethylene terephthalate (LDPE), identical to the packaging in the primary predicate K173207.

The subject device titanium base abutments are to be used with a zirconia superstructure to create the final two-piece abutment. The risks associated with the subject device and the corresponding zirconia superstructure parameters, including angulation, have been mitigated by the mechanical testing provided in this submission. Similarly, the risks associated with the subject device pre-milled blank abutments and the corresponding final design parameters, including angulation, have been mitigated by the mechanical testing provided in this submission.

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 and the primary predicate device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

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

The basis for the belief of SIC invent AG that the subject device is substantially equivalent to the predicate device and the reference devices is summarized in the following *Table of Substantial Equivalence.*

Table of Substantial Equivalence

Comparison	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	K252904 **SIC invent CAD/CAM System** **SIC invent AG**	**K173207** **SIC invent Dental Implant Systems** **SIC invent AG**	**K210489** **SICtapered & SICvantage tapered** **SIC invent AG**	**K240208** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K233316** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K202026** **Blue Sky Bio CAD-CAM Abutments** **Blue Sky Bio, LLC**
Indications for Use Statement	SIC CAD/CAM Products are intended for use with SIC Dental Implants for prosthetic restorations from single tooth replacements to full arch restorations with fixed or removable superstructures. The Bonding Bases consist of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment. All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Bonding Base or Milling Blank are to be sent to an SIC invent validated milling center for manufacture.	SICmax onepiece implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICmax onepiece Implants are indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. Splinting with several implants or the residual dentition is possible. SICmax onepiece implants are also indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading. SICace Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICace Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading. - Only applicable for SICace implants with Ø 3.4 mm: Use without splinting is permissible in the anterior and premolar region. In the molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme. SICmax Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICmax Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading. - Only applicable for SICmax implants with Ø 3.7 mm: Use without splinting is permissible in the anterior and premolar region. In the molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme. SICvantage max Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICvantage max Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading. - Only applicable for SICvantage max implants with Ø 3.0 mm: Use without splinting is permissible in the anterior region for replacement of maxillary lateral incisors	SICtapered SICtapered Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICtapered Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading. Only applicable for SICtapered implants with Ø 3.7 mm Use without splinting is permissible in the anterior and premolar region. In the molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme. SICvantage tapered SICvantage tapered Implants are intended for use during dental implantation and oro-maxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICvantage tapered Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading. Only applicable for SICvantage tapered implants with Ø 3.0 mm Use without splinting is permissible in the anterior region for replacement of maxillary lateral incisors and mandibular incisors. In the premolar and molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme.	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. All digitally designed custom abutments for use with DESS Ti Base abutments or Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K204208.*	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. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K233316.*	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.

Comparison	Subject Device **K252904** **SIC invent CAD/CAM System** **SIC invent AG**	Predicate Device **K173207** **SIC invent Dental Implant Systems** **SIC invent AG**	Reference Device **K210489** **SICtapered & SICvantage tapered** **SIC invent AG**	Reference Device **K240208** **DESS Dental Smart Solutions** **Terrats Medical SL**	Reference Device **K233316** **DESS Dental Smart Solutions** **Terrats Medical SL**	Reference Device **K202026** **Blue Sky Bio CAD-CAM Abutments** **Blue Sky Bio, LLC**
		and mandibular incisors. In the premolar and molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme. SIC Prosthetic Components are intended for use with SIC Dental Implants for prosthetic restorations from single tooth replacements to full arch restorations with fixed or removable superstructures. SIC Prosthetic Components with a post height less than 4 mm are intended for multi-unit loaded restorations only.				
Reason for Predicate / Reference Device	Not applicable	Materials, manufacturing, biocompatibility, sterilization, compatible implant designs	Compatible implant designs	Abutment designs	Abutment designs	Abutment designs
Product Codes	NHA	DZE, NHA	DZE	NHA	NHA	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
Subject Abutments / Compatible Implants						
Internal Hex Implant-Abutment Interface	*Subject device abutments are compatible with these SIC invent Internal Hex implants* Body diameter / Platform diameters: 3.4 mm, 3.7 mm / 3.3 mm 4.0 mm, 4.2 mm / 3.3 mm 4.5 mm, 4.7 mm / 4.2 mm 5.0 mm, 5.2 mm / 4.2 mm Implant lines: SICace®, SICmax®, SICtapered	*SIC invent Internal Hex implants* Body diameter / Platform diameters: 3.4 mm, 3.7 mm / 3.3 mm 4.0 mm, 4.2 mm / 3.3 mm 4.5 mm, 4.7 mm / 4.2 mm 5.0 mm, 5.2 mm / 4.2 mm Implant lines: SICace®, SICmax®	*SIC invent Internal Hex implants* Body diameter / Platform diameters: 3.7 mm / 3.3 mm 4.2 mm / 3.3 mm 4.7 mm / 4.2 mm 5.2 mm / 4.2 mm Implant line: SICtapered			
Internal Taper Implant-Abutment Interface	*Subject abutments are compatible with these SIC invent Internal Taper implants* Body diameter / Prosthetic Connection: 3.0 mm / 2.2 mm 3.7 mm / 2.5 mm 4.2 mm, 4.7 mm, 5.2 mm / 2.9 mm Implant lines: SICvantage® max, SICvantage® tapered	*SIC invent Internal Taper implants* Body diameter/ Prosthetic Connection: 3.0 mm / 2.2 mm 3.7 mm / 2.5 mm 4.2 mm, 4.7 mm, 5.2 mm / 2.9 mm Implant line: SICvantage® max	*SIC invent Internal Taper implants* Body diameter / Prosthetic Connection: 3.0 mm / 2.2 mm 3.7 mm / 2.5 mm 4.2 mm, 4.7 mm, 5.2 mm / 2.9 mm Implant line: SICvantage® tapered			

Comparison	Subject Device **K252904** **SIC invent CAD/CAM System** **SIC invent AG**	Predicate Device **K173207** **SIC invent Dental Implant Systems** **SIC invent AG**	Reference Device **K210489** **SICtapered & SICvantage tapered** **SIC invent AG**	Reference Device **K240208** **DESS Dental Smart Solutions** **Terrats Medical SL**	Reference Device **K233316** **DESS Dental Smart Solutions** **Terrats Medical SL**	Reference Device **K202026** **Blue Sky Bio CAD-CAM Abutments** **Blue Sky Bio, LLC**
Abutment Designs/Features						
Restoration	Single-unit Multi-unit	Single-unit Multi-unit		Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained		Cement-retained, Screw-retained	Cement-retained, Screw-retained	Cement-retained, Screw-retained
Ti Base Abutments						
Prosthetic Platform Diameter	3.3 mm – 4.5 mm			3.85 – 7.0 mm		3.9 – 6.5 mm
Gingival Height (in the base)	0.3 mm – 3.0 mm			0.3 – 3.0 mm		*Not in the 510(k) Summary*
Base Abutment Angulation (in the base)	0° all bases; 15° bases for internal hex connection implants			0°		0°, 15°
Coping Design Parameters						
Minimum wall thickness	0.5 mm			0.4 mm		0.5 mm
Minimum abutment post height for single-unit restorations (abutment post height measured above the gingival height of the final patient-matched design)	4.0 mm			4.2 mm		4.0 mm
Minimum gingival height	0.3 mm			0.5 mm		0.5 mm
Maximum gingival height	4.0 mm			6.0 mm		6.7 mm
Abutment Angulation	**Ti Bases for internal hex implants** 15° in coping for the Angled Ti Base Abutments (with 15° additional angulation in the base); 30° in coping for straight Ti Base Abutments **Ti Bases for internal conical implants** 0°, final abutment is straight only			Up to 30°		15° in coping for the Angled Ti Base abutments (that have 15° additional angulation in the base); 30° in coping for straight Ti Base abutments
Pre-Milled Blank Abutments						
Prosthetic Platform Diameter	Defined by available interproximal space			Defined by available interproximal space		Defined by available interproximal space
Blank Abutments – Final Design Parameters						
Minimum wall thickness	0.5 mm			0.45 mm		0.4 mm
Minimum abutment post height for single-unit restorations (abutment post height measured above the gingival height of the final patient-matched design)	4.0 mm			4.0 mm		4.0 mm
Minimum gingival height	Internal Hex connection 0.3 mm Internal Taper connection 0.5 mm			0.5 mm		0.5 mm
Maximum gingival height	3.0 mm			6.0 mm		6.7 mm
Angulation of Finished Abutment	Up to 30°			Up to 30°		Up to 30°

Comparison	Subject Device **K252904** **SIC invent CAD/CAM System** **SIC invent AG**	Predicate Device **K173207** **SIC invent Dental Implant Systems** **SIC invent AG**	Reference Device **K210489** **SICtapered & SICvantage tapered** **SIC invent AG**	Reference Device **K240208** **DESS Dental Smart Solutions** **Terrats Medical SL**	Reference Device **K233316** **DESS Dental Smart Solutions** **Terrats Medical SL**	Reference Device **K202026** **Blue Sky Bio CAD-CAM Abutments** **Blue Sky Bio, LLC**
Multi-Unit Abutments						
Abutment-Implant Connection (Platform)	*Subject Multi-Unit Abutments are only for SIC invent Internal Hex implants* 3.3 mm, 4.2 mm	*For SIC invent Internal Taper implants* 2.5, 2.9		3.5 mm, 4.3 mm, 4.5 mm	3.0 – 5.7 mm	
Prosthetic Platform Diameter	3.75 mm	5.0 mm		4.8 mm	*Not stated in the 510(k) Summary*	
Gingival Height (in the MUA)	1.5 mm, 3.0 mm	1.5 mm, 3.0 mm		0.8 – 5.5 mm	1 – 6 mm for 0° 2.5 – 4.5 mm for 17° 3.5 – 5.5 mm for 30°	
Abutment Angulation, (in the MUA)	0°	0°, 16°, 30°		0°, 17°, 30°	0°, 17°, 30°	
Angulation of Finished Abutment with Coping	0°	0°, 16°, 30° (no additional angulation in coping)		0°, 17°, 30° (no additional angulation in coping)	0°, 17°, 30° (no additional angulation in coping)	
Temporary Abutments						
Abutment-Implant Connection (Platform)	*Subject Temporary Abutments are only for SIC invent Internal Hex implants* 3.3 mm, 4.2 mm			3.0 – 5.1 mm	2.52 – 5.7 mm	
Prosthetic Platform Diameter	3.6 mm, 4.5 mm			*Not stated in the 510(k) Summary*	4.5 – 6.8 mm	
Gingival Height	0.5 mm			1.5 mm	0.35 – 2.5 mm	
Angulation	0°			0°	0°	
Materials						
Abutment material (prefabricated titanium base, and pre-milled blank)	Ti-6Al-4V (ASTM F136, ISO 583203)	Ti-6Al-4V (ASTM F136, ISO 583203)		Ti-6Al-4V (ASTM F136) Co-Cr-Mo (ASTM F1537)	Ti-6Al-4V (ASTM F136)	Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537
Superstructure material	Zirconia (Y-TZP), ISO 13356			Zirconia (Y-TZP)		Zirconia, ISO 13356
Required cement to bond zirconia superstructure to the abutment base	3M ESPE RelyX Unicem bonding cement (cleared in K022476)			Multilink Hybrid Abutment Cement, (Ivoclar Vivadent AG)		Multilink Hybrid Abutment Cement, (Ivoclar Vivadent AG)
Abutment screws	Ti-6Al-4V (ASTM F136, ISO 583203)	Ti-6Al-4V (ASTM F136, ISO 583203)		Ti-6Al-4V alloy	Ti-6Al-4V (ASTM F136)	*Not in the 510(k) Summary*
How Provided						
Sterilization	Non-sterile	Sterile by gamma irradiation (implants) Non-sterile (abutments)	Sterile by gamma irradiation	Sterile by gamma irradiation, and Non-sterile	Sterile by gamma irradiation, and Non-sterile	*Not in the 510(k) Summary*