March 17, 2022

SIC invent AG
Cretia McNett
Chief Regulatory Officer
Birmannsgasse 3
Basel, CH-4055
SWITZERLAND

Re: K210489
Trade/Device Name: SICtapered & SICvantage tapered
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 7, 2022
Received: February 17, 2022

Dear Cretia McNett:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K210489

Device Name
SICtapered & SICvantage tapered

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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***SIC invent AG***
SICtapered & SICvantage tapered
510(k) Premarket Notification

**DATE PREPARED:** March 17, 2022

**APPLICANT:**

SIC invent AG
Birmannsgasse 3
4055 Basel
Switzerland
Tel: + 49 55150429440
Mobile: +49 15121349184
E-Mail: Cretia.McNett@sic-invent.com

**CONTACT PERSON:**

Cretia McNett
Chief Regulatory Officer
Tel: + 49 55150429440
E-Mail: Cretia.McNett@sic-invent.com

## 1 Device Name

| | |
|---|---|
| Trade Name: | *SICtapered & SICvantage tapered* |
| Common Name: | *SICtapered & SICvantage tapered* |
| Device Classification Name: | *Endosseous dental implant* |

## 2 Classification / Product Code

SICtapered & SICvantage tapered can be classified according to following device name and product code:

| Device | Regulation Description | Regulation Medical Specialty | Review Panel | Product Code | Regulation Number | Device Classification |
|---|---|---|---|---|---|---|
| SICtapered | Endosseous dental implant | Dental | Dental | DZE | 872.3640 | 2 |
| SICvantage tapered | Endosseous dental implant | Dental | Dental | DZE | 872.3640 | 2 |

## 3 Predicate Device / Reference Device

| Device | Predicate Device | Reference Device | Reference Device 2 | 510(k) Number | 510(k) Holder |
|---|---|---|---|---|---|
| SICtapered | SICmax | --- | | K173207 | SIC invent AG |
| SICvantage tapered | SICvantage max | --- | | K173207 | |
| SICtapered Ø 3.7 mm / 7.25 mm | --- | Legacy3 6mm Length Implants | --- | K131097 | Implant Direct Sybron Manufacturing Llc |
| SICvantage tapered Ø 3.0 mm / 9.25 mm | --- | --- | OsseoSpeed Profile EV Ø 3.0 mm / 8.00 mm (previously named OsseoSpeed Plus) | K120414 | Dentsply Implants Manufacturing GmbH (previously Astra Tech AB) |

# 4 Device Description

## 4.1 Dental implant SICtapered

The SICtapered is a two-part, self-tapping, endosteal threaded implant. The basic shape is conical with an initially tapered "apical cutting edge". The cortical area is cylindrical, and the core diameter is increased. On the top of the implant, there is a decompression zone to reduce the compression on the bone and a crestal bevel designed for "platform switching". The apex has an aggressive cut with a large flute for good chip clearance. The vertical fixation screw is secured with a torque of 20 Ncm. The implants are manufactured from medical-grade pure titanium (ISO 5832-2). The microstructuring of the surface is achieved by abrasive processes. Surgical accessories and prosthetic abutments are usually color-coded by means of anodized oxidation.

Implant Sizes:

| Diameter [mm] | Length [mm] | Length [mm] | Length [mm] | Length [mm] | Length [mm] |
|---|---|---|---|---|---|
| 3.70 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |
| 4.20 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |
| 4.70 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |
| 5.15 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |

The table shows which implant body combinations are available.

## 4.2 Dental implant SICvantage tapered

The SICvantage tapered is a two-part, self-tapping, endosteal threaded implant. The basic shape is conical with an initially tapered „apical cutting edge". The cortical area is cylindrical, and the core diameter is increased. On the top of the implant, there is a decompression zone to reduce the compression on the bone and a crestal bevel designed for "platform switching". The apex has an aggressive cut with a large flute for good chip clearance. The SICvantage tapered can be used in all bone qualities (D1 – D4). The implants are manufactured from medical-grade pure titanium (ISO 5832-2). The microstructuring of the surface is achieved by abrasive processes. Surgical accessories and prosthetic abutments are usually color-coded by means of anodized oxidation.

Implant Sizes:

| Diameter [mm] | Length [mm] | Length [mm] | Length [mm] | Length [mm] | Length [mm] |
|---|---|---|---|---|---|
| 3.00 | 9.25 | 11.25 | 12.75 | 14.25 | N/A |
| 3.70 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |
| 4.20 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |
| 4.70 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |
| 5.15 | 7.25 | 9.25 | 11.25 | 12.75 | 14.25 |

The table shows which implant body combinations are available.

## 4.3 Compatibility

The FDA-cleared abutments from K173207 are compatible with the above-mentioned SICtapered and SICvantage tapered implants. The SICvantage tapered implants with smallest diameter of Ø3.0 mm are only available to be compatible with FDA-cleared abutments from K173207 with angulation up to 15° under single-unit loading, while the SICtapered and SICvantage tapered dental implants with larger diameter implants (≥ Ø3.7 mm) are compatible with FDA-cleared abutments from K173207 up to 25° angulation under single-unit loading.

# 5 Indications for Use

**SICtapered**

SICtapered 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. 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.

# 6 Technological Characteristics

The technological characteristics of SICtapered are the same as the technological characteristics of the predicate device SICmax.

The technological characteristics of SICvantage tapered are the same as the technological characteristics of the predicate device SICvantage max.

## 6.1 Device Characteristics Table

**SICtapered**

| Company | SIC invent AG (New Device) | SIC invent AG (Predicate Device) | Result |
|---|---|---|---|
| **Device Name** | SICtapered | SICmax | - |
| **Regulation Number** | 872.3640 | 872.3640 | Same |
| **Class** | 2 | 2 | Same |
| **Code** | DZE | DZE | Same |
| **510(k) number** | K210489 | K173207 | - |
| **Indications for Use** | 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. | 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. | Same |
| **Type of Body Contact** | Direct | Direct | Same |
| **Category of Body Contact** | Implant devices | Implant devices | Same |
| **Contact of Body Contact** | Hard tissues, soft tissues, blood, saliva | Hard tissues, soft tissues, blood, saliva | Same |
| **Duration of Body Contact** | C – Permanent (>30 d) | C – Permanent (>30 d) | Same |
| **Implant Diameter [mm]** | 3.70 / 4.20 / 4.70 / 5.15 | 3.70 / 4.20 / 4.70 / 5.15 | Same |
| **Implant Length [mm]** | 7.25 / 9.25 / 11.25 / 12.75 / 14.25 | 7.50 / 9.50 / 11.50 / 13.00 / 14.50 | Substantially equivalent, except for 7.25 mm length, see comparison to K131097 reference device below |
| **Implant Connection [Index]** | Inner hexagon | Inner hexagon | Same |
| **Index positions** | 6 | 6 | Same |
| **Size of connection [mm]** | HEX 2.30 mm | HEX 2.30 mm | Same |
| **Connection height [mm]** | 2.2 mm | 2.2 mm | Same |
| **Inner thread** | M1.6x0.25 | M1.6x0.25 | Same |
| **Prosthetic sizes [mm]** | 3.3 mm and 4.2 mm | 3.3 mm and 4.2 mm | Same |
| **Design** | Two-piece | Two-piece | Same |
| **Surface Treatment** | Sandblasted, Etched | Sandblasted, Etched | Same |
| **Material** | Titanium Grade 4 (3.7065) | Titanium Grade 4 (3.7065) | Same |
| **Delivery Status** | Sterile (Irradiation) | Sterile (Irradiation) | Same |

| Company | SIC invent AG (New Device) | Implant Direct Sybron Manufacturing Llc (Reference Device 1) | Result |
|---|---|---|---|
| **Device Name** | SICtapered Ø 3.70 mm / 7.25 mm | Legacy3 6mm Length Implants | - |
| **Regulation Number** | 872.3640 | 872.3640 | Same |
| **Class** | 2 | 2 | Same |
| **Code** | DZE | DZE | Same |

| Company | SIC invent AG (New Device) | Implant Direct Sybron Manufacturing Llc (Reference Device 1) | Result |
|---|---|---|---|
| **510(k) number** | K210489 | K131097 | - |
| **Indications for Use** | 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. | Legacy' 6mm Length consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. | Substantially Equivalent |
| **Type of Body Contact** | Direct | Direct | Same |
| **Category of Body Contact** | Implant devices | Implant devices | Same |
| **Contact of Body Contact** | Hard tissues, soft tissues, blood, saliva | Hard tissues, soft tissues, blood, saliva | Same |
| **Duration of Body Contact** | C – Permanent (>30 d) | C – Permanent (>30 d) | Same |
| **Implant Diameter [mm]** | 3.70 / 4.20 / 4.70 / 5.15 | 3.70 / 4.20 / 4.70 / 5.20 / 5.70 / 7.00 | Same |
| **Implant Length [mm]** | 7.25 | 6.00 | Substantially Equivalent |
| **Implant Connection [Index]** | Inner hexagon | Inner hexagon | Same |
| **Index positions** | 6 | 6 | Same |
| **Size of connection [mm]** | HEX 2.30 mm | Hex | Substantially Equivalent |
| **Prosthetic sizes [mm]** | 3.3 mm and 4.2 | 3.0, 3.5, 4.5, 5.7 | Substantially equivalent |
| **Design** | Two-piece | Two-piece | Same |
| **Surface Treatment** | Sandblasted, Etched | SBM Blasted, HA Coated | Substantially Equivalent |
| **Material** | Titanium Grade 4 (3.7065) | Titanium Grade 4 (3.7065) | Same |
| **Delivery Status** | Sterile (Irradiation) | Sterile (Irradiation) | Same |

## SICvantage tapered

| Company | SIC invent AG (New Device) | SIC invent AG (Predicate Device) | Result |
|---|---|---|---|
| **Device Name** | SICvantage tapered | SICvantage max | - |
| **Regulation Number** | 872.3640 | 872.3640 | Same |
| **Class** | 2 | 2 | Same |
| **Code** | DZE | DZE | Same |
| **510(k) number** | K210489 | K173207 | - |

| Company | SIC invent AG (New Device) | | SIC invent AG (Predicate Device) | | Result |
|---|---|---|---|---|---|
| **Indications for Use** | 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. | | 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 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 | | Same |
| **Type of Body Contact** | Direct | | Direct | | Same |
| **Category of Body Contact** | Implant devices | | Implant devices | | Same |
| **Contact of Body Contact** | Hard tissues, soft tissues, blood, saliva | | Hard tissues, soft tissues, blood, saliva | | Same |
| **Duration of Body Contact** | C – Permanent (>30 d) | | C – Permanent (>30 d) | | Same |
| **Implant Diameter [mm]** | 3.0 | 3.70 / 4.20 / 4.70 / 5.15 | 3.0 | 3.70 / 4.20 / 4.70 / 5.15 | Same |
| **Implant Length [mm]** | 9.25 / 11.75 / 12.75 / 14.25 | 7.25 / 9.25 / 11.25 / 12.75 / 14.25 | 9.50 / 11.50 / 13.00 / 14.50 | 7.50 / 9.50 / 11.50 / 13.00 / 14.50 | Substantially equivalent,<br>- except for 9.25 mm length for 3.0 mm diameter, see comparison to K120414 reference device below<br>- except for 7.25 mm length for 3.70, 4.20, 4.70, and 5.15 mm diameters, see comparison to K131097 reference device above |
| **Implant Connection [Index]** | Morse taper with swiss cross | | Morse taper with swiss cross | | Same |
| **Index positions** | 4 | | 4 | | Same |
| **Size of connection [mm]** | 2.2 / 2.5 / 2.9 mm cone | | 2.2 / 2.5 / 2.9 mm cone | | Same |
| **Connection height [mm]** | 4.3 mm | | 4.3 mm | | Same |
| **Inner thread** | M1.6x0.25 | | M1.6x0.25 | | Same |
| **Prosthetic sizes [mm]** | 2.2 mm, 2.5 mm and 2.9 mm | | 2.2 mm, 2.5 mm and 2.9 mm | | Same |
| **Design** | Two-piece | | Two-piece | | Same |
| **Surface Treatment** | Sandblasted, Etched | | Sandblasted, Etched | | Same |
| **Material** | Titanium Grade 4 (3.7065) | | Titanium Grade 4 (3.7065) | | Same |
| **Delivery Status** | Sterile (Irradiation) | | Sterile (Irradiation) | | Same |

| Company | SIC invent AG (New Device) | Dentsply Implants Manufacturing GmbH (Reference Device 2) | Result |
|---|---|---|---|
| **Device Name** | SICvantage tapered Ø 3.0 mm / 9.25 mm | OsseoSpeed EV Ø 3.0 mm / 8.00 mm | - |
| **Regulation Number** | 872.3640 | 872.3640 | Same |
| **Class** | 2 | 2 | Same |
| **Code** | DZE | DZE | Same |
| **510(k) number** | K210489 | K120414 | - |

| Company | SIC invent AG<br>(New Device) | Dentsply Implants Manufacturing GmbH<br>(Reference Device 2) | Result |
|---|---|---|---|
| **Indications for Use** | 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. | The implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:<br>• Replacing missing teeth in single or multiple unit applications in the mandible or maxilla.<br>• Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.<br>• Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective.<br>• Immediate and early loading for all indications, except in single tooth situations on implant shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.<br>The intended use for OsseoSpeed EV 3.0 S is limited to placement of maxillary lateral incisors and mandibular incisors. | Substantially Equivalent |
| **Type of Body Contact** | Direct | Direct | Same |
| **Category of Body Contact** | Implant devices | Implant devices | Same |
| **Contact of Body Contact** | Hard tissues, soft tissues, blood, saliva | Hard tissues, soft tissues, blood, saliva | Same |
| **Duration of Body Contact** | C – Permanent (>30 d) | C – Permanent (>30 d) | Same |
| **Implant Diameter [mm]** | 3.0 | 3.0 | Same |
| **Implant Length [mm]** | 9.25 | 8.00 | Substantially Equivalent |
| **Implant Connection [Index]** | Morse taper with swiss cross | Unique interface (taper with rotation lock) | Substantially Equivalent |
| **Design** | Two-piece | Two-piece | Same |
| **Surface Treatment** | Sandblasted, Etched | Blasted, etched | Substantially Equivalent |
| **Material** | Titanium Grade 4 (3.7065) | Titanium Grade 4 (3.7065) | Same |
| **Delivery Status** | Sterile (Irradiation) | Sterile (Irradiation) | Same |

## 6.2 Summary of Technological Characteristics

The proposed devices are similar in terms of design, operating principles and intended use and have similar technological characteristics as the predicate devices. The materials used on these devices are also used in the legally marketed predicate devices.

# 7 Performance Data

Non-clinical testing has been performed showing that the device (SICtapered & SICvantage tapered) performs as intended and are substantially equivalent to the predicate device (K173207)

In summary, the following tests were performed:

| Test Type | Description | Results |
|---|---|---|
| **Dosemapping** | The sterilization procedure, packaging, material and surface treatment of the new device and predicate device are exactly the same. Therefore, the Dosemapping of predicate device SICmax was leveraged for the new device. | Passed according to defined criteria with no unexpected results or significant deviations. |
| **Cytotoxicity** | The new device and predicate device are made of the same material and the surface treatment is exactly the same. Therefore, the Cytotoxicity tests according to ISO 10993-5 and 10993-12 of predicate device SICmax was leveraged for the new device. | Passed according to defined criteria with no unexpected results or significant deviations. |
| **Bioburden** | The new device and predicate device are made of the same material and the surface treatment is exactly the same. Therefore, the Bioburden tests of predicate device SICmax was leveraged for the new device. | Passed according to defined criteria with no unexpected results or significant deviations. |
| **Sterility** | The sterilization procedure, packaging, material and surface treatment of the new device and predicate device are exactly the same. Therefore, the Sterility tests of predicate device SICmax was leveraged for the new device. | Passed according to defined criteria with no unexpected results or significant deviations. |
| **Shelf Life** | The sterilization procedure, packaging, material and surface treatment of the new device and predicate device are exactly the same. Therefore, the Shelf Life tests of predicate device SICmax was leveraged for the new device. | Passed according to defined criteria with no unexpected results or significant deviations. |
| **Packaging Validation** | The sterilization procedure and packaging of the new device and predicate device are exactly the same. Therefore, the Packaging Validation tests of predicate device SICmax was leveraged for the new device. | Passed according to defined criteria with no unexpected results or significant deviations. |
| **Fatigue Test – Mechanical Test** | Dynamic loading test for endosseous dental implants according to EN ISO 14801 was performed on the worst case for SICtapered as well as the worst case for SICvantage tapered devices. | Passed according to defined criteria with no unexpected results or significant deviations. |

## 7.1 Biocompatibility

The devices (SICtapered & SICvantage tapered) are made of Titanium Grade 4 according to ISO 5832-2 / ASTM F67. This standard specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants. Cytotoxicity testing according to ISO 10993-5 and ISO 10993-12 have been successfully performed on SICtapered and SICvantage tapered devices.

Based on the evaluation of the material constituent to the devices, SIC invent AG Dental Implants SICtapered & SICvantage tapered meet the requirements of ISO 10993:2009 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process). The biological safety of the device is therefore considered to be satisfactorily demonstrated.

## 7.2 Sterilization and Shelf Life

SIC invent AG Dental Implants SICtapered & SICvantage tapered are delivered in a sterile state. Irradiation sterilization has been validated. Performed validation and revalidations according to harmonized standards are able to demonstrate the validity of the process and a sterility assurance level (SAL) of $10^{-6}$.

Both Sterile Barrier System for Dental Implants and Shelf life have been validated. Performed tests in accordance with harmonized standards are able to demonstrate packaging safety of our devices. Manufacturer claims related to 5-year device shelf life as well as the suitability of sterile barrier system are confirmed.

The same tests that were used with rational confirmation remain applicable. For sterilization and shelf life, reference can be made to the products tested in the course of K173207, as they are comparable to the SICtapered & SICvantage tapered implants.

# 8 Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, SIC invent AG dental implants SICtapered and SICvantage tapered are considered to be substantially equivalent to the predicate device SICmax and SICvantage max respectively in terms of indication for use, materials and technology, design and performance specifications. There are no differences between the devices which would raise new issues of safety or effectiveness.