January 29, 2025

Surcam Medical Devices and Developments Ltd
% Angela Blackwell
senior consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K242217
Trade/Device Name: Surcam Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 6, 2025
Received: January 7, 2025

Dear Angela Blackwell:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Andrew I. Steen -S

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K242217

Device Name
Surcam Dental Implant System

Indications for Use *(Describe)*
The Surcam Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The C Type and S Type 3.3mm diameter implants are indicated for use with only straight abutments.
Temporary cylinders must be used in a splinted restoration only and are not for single crown restorations.

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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**510k Summary K242217**
**January 28, 2025**
**Surcam Dental Implant System**

**Name and address of Submitter:** Surcam
Northern Industrial Zone P.O.B. 12084
Nahariya 2201202 Israel
**Contact Person:** Shay Ben Shabat
**Phone Number:** +972 4 9523511
**Name of device:** Surcam Dental Implant System
**Classification Name:** Endosseous dental implants
**CFR:** 21 CFR 872.3640
**Primary Product Code:** DZE
**Secondary Product Code:** NHA

**Submission Contact:**
Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

**Device Description:** The Surcam Dental Implant System consists of endosseous dental implants in conical and internal hex connections along with abutments, cover screws, healing caps and abutment systems for each connection type. Conical devices come in two platforms, NP and RP. Implants and abutments are made from ASTM F136 Ti6AL4V ELI. Multi-unit abutments are for multi-unit restorations only.

The Surcam Dental Implant System includes:

Conical Connection Devices

Conical connection implants and abutments should be matched by platform size of either NP or RP.

LSA Implants 3.5, 4.3, 5.0mm diameter in lengths of 8,10,11.5,13 and 15mm (no 15 in 5.0)

Cover Screw NP 3.0 x 4.0mm

Cover Screw RP 6.0 x 3.5mm

Healing Cap NP 3.6 x 2.95, 4.95, 6.95mm height above platform, total heights 8.3, 10.3, 12.3mm
Healing Cap NP 5.0 x 2.95, 4.95, 6.95mm height above platform, total heights 8.3, 10.3, 12.3mm
Healing Cap RP 3.6 x 2.95, 4.95, 6.95mm height above platform, total heights 8.3, 10.3, 12.3mm

Healing Cap RP 5.0 x 2.8, 4.8, 6.8mm height above platform, total heights 8.3, 10.3, 12.3mm

Angled Abutment 15° GH 1.5mm NP 4.2 x 10.3mm total height, 7.95mm height above platform
Angled Abutment 15° G H3.0mm NP 4.2 x 11.8mm total height, 9.45mm height above platform
Angled Abutment 15° GH 1.5mm RP 5.0 x 10.3mm total height, 7.3mm height above platform
Angled Abutment 15° GH 2.9mm RP 5.0 x 11.8mm total height, 9.3mm height above platform

Straight Titanium Anatomic GH 1.48 mm Abutment 3.0x 10.3mm total height, 7.8mm height above platform NP
Straight Titanium Anatomic GH 1.4mm Abutment 5.0 x 10.3mm total height, 7.8mm height above platform RP
Straight Titanium Anatomic GH 2.9mm Abutment 3.0 x 11.8mm total height, 9.45mm height above platform NP
Straight Titanium Anatomic GH 2.9mm Abutment 5.0 x 11.8mm total height, 9.3mm height above platform RP

Straight Multi-Unit NP GH 1.35, 2.35, 3.35, 4.35, 5.35mm 3.0 x 9, 10, 11, 12, 13mm total height, 2.15mm height above platform
Straight Multi-Unit RP GH 1.3, 2.3, 3.3, 4.3, 5.3mm 4.3 x 9, 10, 11, 12, 13mm total height, 2.15mm height above platform

Healing Cap for multi-unit 5.0 x5.0mm
Short sleeve for multi-unit 5.0 x 4.41mm
Titanium sleeve for multi-unit 6.0 x 12mm
Screw for multi-unit sleeve
Longer screw for multi-unit sleeve
Screw for conical multi-unit and abutments NP
Screw for conical multi-unit RP
Conical abutment screw RP
Conical abutment screw NP

Internal Hex Connection Devices

Internal hex implants and abutments only come in one platform so all abutments will fit all implants. Temporary abutments are for use less than 180 days. C & S Type 3.3mm implants are for use with straight abutments only.

S-Type Implant 3.3, 3.75, 4.2, 5.0, 6.0mm diameter in lengths of 8, 10, 11.5, 13, 16 (not in 3.3 or 6.0), 18 (3.75 and 4.2 only) mm

C-Type Implant 3.3, 3.75, 4.2, 5.0, 6.0mm diameter in lengths of 8, 10, 11.5, 13, 16 (not in 5.0 or 6.0), 18 (3.75 only) mm

Cover Screw internal hex

Concave healing cap 5.5 x 7.95, 8.95, 9.95, 10.95mm total height 2.75, 3.75, 4.75, 5.75 height above platform For 5.0mm diameter implants
Healing cap slim 4.5 x 8.2, 9.2, 10.2, 11.2, 12.2mm total height 3.17, 4.17, 5.17, 6.17, 7.17mm height above platform For 4.2mm diameter implants
Healing cap 5.5 x 7.5, 8.1, 9.05, 10.05, 11.05mm total height 2,3,4,5,6mm height above platform For 5.0mm diameter implants
Healing cap slim 4.5 x 9.05, 10.05mm total height 4,5mm height above platform For 4.2mm diameter implants
Healing cap extra slim 3.5 x 6.9, 7.9, 8.9mm total height 2,3,4mm height above platform For 3.3 and 3.75mm diameter implants
Healing cap wide 6.3 x 8, 9, 9.6mm total height 3,4,5mm height above platform For 6.0mm diameter implants

Straight multi-unit 5.0 x 8.5, 9.5, 10.5, 11.5, 12.5mm total height
GH 1.2,2.2,3.2,4.2,5.2mm 2.2mm height above platform

Straight multi-unit 5.0 x 9, 10, 10.7, 11.7, 12.7mm total height GH 1.17,2.17,3,4,5mm 2.2mm height above platform

Angled multi-unit 18° 3.75mm diameter GH .55, 1.35, 2.62mm 5.7, 6.5, 7.8mm total height

18° overdenture abutment 3.75mm diameter GH .54, 1.3, 2.35, 3.57mm 5.7, 6.5, 7.6, 8.85mm total height

Healing Cap for multi-unit 5.0 x 5.0mm
Short sleeve for multi-unit 5.0 x 4.1mm
Titanium sleeve for multi-unit 6.0 x 12mm
Screw for multi-unit sleeve
Longer screw for multi-unit sleeve
Internal hex abutment screw
Internal hex multi-unit screw

Straight Curve Concave Abutments 3.75mm diameter GH 1,2,3,4mm 11, 12, 13, 14mm total height
Straight anatomic abutment 3.75mm diameter GH 1,2,3,3.7mm 11, 12, 13, 14mm total height
Straight wide anatomic abutment 4.5mm diameter GH 1,2,2.7mm 11, 12, 13mm total height
Straight shoulder abutment 3.75mm diameter GH 1.15,2.15,3 mm 11, 12, 13mm total height

15° Concave Curve Abutment GH 1.05,2,3,4mm 11, 12, 13, 14mm total height
25° Concave Curve Abutment GH 1,2,3,4mm 11, 12, 13, 14mm total height

15° Anatomic Abutment 3.75mm diameter GH 1,1.9,3,3.7mm 11, 12, 12.5, 13.7mm total height

25° Anatomic Abutment 3.75mm diameter GH 1,2,3,4mm 11, 12, 12.8, 13.5mm total height

15° Wide Anatomic Abutment 4.5mm diameter GH 1.25,2mm 11, 12mm total height

15° Smooth abutment 3.75mm diameter Total height of 9, 11, 13.5mm gingival height 1,1,1.5mm Post height 5.93, 7, 8mm

15° Smooth thin abutment 3.75mm diameter total height 11mm gingival height 0.5mm Post height 9mm

15° Smooth wide abutment 4.5mm diameter total height 11mm gingival height 1.5mm Post height 7mm

25° Smooth abutment 3.75mm diameter Total height 9.5, 11, 13.5mm Gingival height 1.5, 1, 2.8mm Post height 8, 8, 9mm

**Indications for Use:** The Surcam Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The C Type and S Type 3.3mm diameter implants are indicated for use with only straight abutments.
Temporary cylinders must be in a splinted restoration only and are not for single crown restorations.

**Testing Summary:** Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments are strong enough for their intended use. Surface cleanliness analysis of the implants was done and all tests were passed. Sterilization validation according to ISO 11137-1 and 11137-2 was conducted on the implants. Abutment steam sterilization validation was done according to ISO 17665-1 and -2. Materials used in the product meet ASTM F136. Endotoxin testing according to USP 161 was conducted. Shelf life and package integrity testing were conducted according to ASTM F1980 ASTM F1929, ASTM 2338, ASTM D3078 and ISO 11607-1. The shelf life is 5 years.

**MR Environment Condition**

Non-clinical worst-case MRI review was performed to evaluate the metallic Surcam Dental Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

**Predicate Device:** Surgikor Dental Implant System K182615
**Reference Devices:** Straumann K191123, Cortex Dental Implants K090709 and K163385 AB Dental Implants K132125, OsseOne K182293, Dentsply Sirona K163350 and Osstem K161604

**Substantial Equivalence:**

The Surcam Dental Implant System is substantially equivalent to Surgikor Dental Implants in indications for use, materials, design, and fatigue performance. Slight differences in implant and angled abutment design between the subject devices and the predicate devices were addressed by showing both had adequate fatigue performance. Larger size implants and abutments as well as some abutment designs needed a reference device. The primary predicate supports the wider diameter subject device (i.e., 6mm). The restriction included in the Indications for use for the primary predicate device pertains to the 7mm diameter implant body only and is not applicable to the subject device implant bodies. The Cortex reference device is used for demonstrating equivalence to some designs and sizes which are not present in the later Cortex predicate submission. The OsseOne, Dentsply Sirona and AB Dental Implants reference devices are used to demonstrate equivalence in abutments designs and heights which are not in the predicate device submission.

| Company & Device Name | Surcam Dental Implant System | Surgikor Dental Implant System K182615 | Cortex Dental Implants K090709 and K163385 | Osstem K161604 |
|---|---|---|---|---|
| Indications for Use | . The Surcam Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The C Type and S Type 3.3mm diameter implants are indicated for | Surgikor's Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the | Cortex Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading for use in surgical (single-stage or two-stage procedures) and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic device such as artificial teeth and to restore the patient's chewing | The Osstem Implant is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra Wide Fixture System is intended to be used in the molar region. |

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| | use with only straight abutments. Temporary cylinders must be in a splinted restoration only and are not for single crown restorations. | patient's chewing function. The Dental Implant System is indicated also for immediat e loading when good primary stability is achieved and with appropriat e occlusal loading. The 7mm implants are intended to be used in the molar region. | function. The system is intended to be used in either single teeth or multiple teeth applications. | |
| Implant Diameters | C Type 3.3, 3.75, 4.2, 5.0, 6.0 mm<br><br>S Type 3.3, 3.75, 4.2, 5.0, 6.0 mm<br><br>LSA (Conical) 3.5, 4.3, 5.0 mm | Versatile Hex 3.5, 3.75, 4.2, 4.5, 5.0, 6.0mm<br><br>Immediat e Hex 3.5, 3.75,4.2, 4.5, 5.0, 6.0, 7.0mm<br><br>Fixation Narrow Platform 3.0mm Fixation Regular | Classix 3.3, 3.8, 4.2, 5.0, 6.0 Conical and Hex<br><br>Dynamix 3.0, 3.3, 3.8, 4.2, 5.0, 6.0 Conical and Hex<br><br>Saturn 3.8, 4.2 Hex<br><br>Magix 3.3, 3.8, 4.2 Conical | Osstem Hex 3.2, 3.5, 3.75, 3.77, 4.2, 4.25, 4.4, 4.45, 4.6, 4.63, 4.65, 4.8, 4.9, 5.05, 5.08, 5.1, 5.25, 6.2, 7.1 mm |

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| | | Platform 3.5, 3.9mm<br>Fixation Wide Platform 4.3, 5.0mm<br><br>Solution5 Narrow Platform 3.25mm<br>Solution5 Regular Platform 3.5, 4.0mm<br>Solution5 Wide Platform 4.5, 5.0, 5.5, 6.0mm<br><br>Solution2 3.25mm | | |
| Implant Lengths | C Type 8, 10, 11.5, 13, 16 mm<br>No 16 in 5 or 6mm diameter.<br>18mm (3.75 only)<br><br>S Type 8, 10, 11.5, 13, 16 mm<br>No 16 in 6mm diameter.<br>18mm (3.75 and 4.2 only)<br><br>LSA (conical) 8, 10, 11.5, 13, 15 mm<br>No 15 in 5mm diameter. | Versatile Hex 8, 10, 11.5, 13, 16, 18 (4.2 only), 20 (4.2 only)mm<br>Immediate Hex 8 (no 3.5 diameter) 10, 11.5, 13, 16mm 7.00 diameter not in 11.5, 13 or 16mm. | Classix 6,8,10,11.5, 13, 16 no 3.3 or 3.8 in 6, no 3.3 in 8, no 5 in 16 and no 6 in 13 or 16<br><br>Dynamix 6,8,10,11.5,13,16 no 3.0 3.3 or 3.8 in 6, no 3.3 or 3.8 in 8, no 13 in 6 and no 5 or 6 in 16<br><br>Saturn 8,10,11.5,13,16<br><br>Magix | Osstem 6.2,7.0,8.5,10,11.5,13,15,18 |

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| | | Fixation Narrow Platform 10, 11.5, 13, 15mm<br>Fixation Regular Platform 8.5, 10, 11.5, 13, 15, 18mm<br>Fixation Wide Platform 8.5, 10, 11.5, 13, 15, 18mm<br><br>Solution5 Narrow Platform 10,11.5, 13, 15mm<br>Solution5 Regular Platform 7.0 (4.0 diameter only), 8.5, 10, 11.5, 13, 15mm<br>Solution5 Wide Platform 7.0, 8.5, 10, 11.5, 13, 15mm<br><br>Solution2 10, 11.5,13 16mm | 8,10,11.5,13 no 3.3 in 8 | |
| Material of devices included in the submission | Ti-6AL-4V ELI | Ti-6AL-4V ELI | Ti-6AL-4V ELI | Ti-6AL-4V ELI |

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| Type of abutment and maximum angulation | Pre-manufactured abutments of no more than 25° and Multi-Units of no more than 18° | Pre-manufactured abutments of no more than 25° and Multi-Units of no more than 30° | Pre-manufactured of no more than 25° | Pre-manufactured of no more than 25 |
| Interface type/shape | Internal hex, conical | Internal hex, conical | Internal hex, conical | Internal hex |
| Surface Treatment | Alumina blasted and acid etched | HA blasted and double acid etched | Alumina blasted and acid etched | Sand blasted and acid etched |
| Post Surface Treatment Cleanliness Demonstrated | Yes | Yes | Yes | Yes |

| | Surcam Dental Implant System | Surgikor Dental Implant System K182615 | Cortex Dental Implants K090709 & K163385 | OsseOne K182293 | Reference device for individual devices |
|---|---|---|---|---|---|
| **Cover screw** | Cover screws | Cover screws | Cover screws | | |
| **Straight Multi-Unit Abutments in Hex and Conical** | Straight multi-unit conical NP and RP in heights of 1.35, 2.35, 3.35, 4.35, 5.35 in NP platform diameter of 3.0 and in heights of 1.3, 2.3, 3.3, 4.3, 5.3mm in RP platform diameter 4.3mm Height above platform 2.15mm | Multi-unit abutments in heights of 1,2,3 and 4 mm in conical platform diameters of 3.0, 3.5, and 4.3 plus hex platform diameter of 3.75 | Straight Multi-unit Abutments in heights of 1,2,3,4 and 5 mm | | Straumann K191123 straight multi-unit in gingival height of 5.5mm |

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| | Straight multi-unit IH in gingival heights of 1.2, 2.2, 3.2, 4.2, 5.2 mm in diameter 5.0mm and in gingival heights of 1.17,2.17.3,4,5mm diameter 5.0mm Height above platform 2.2mm | Height above platform 2.2mm | | | |
| **18° Angled Multi-Unit Abutments** | IH Multi System Angled multi-unit 18° in 3.75mm diameter in regular and overdenture versions. With total heights of 5.7, 6.5, 7.8mm for regular and 5.7, 6.5, 7.6, 8.85mm for overdenture and with gingival heights of 0.55, 1.35, 2.63mm for regular and 0.54, 1.3, 2.35, 3.57mm for overdenture. | Multi-unit abutments in heights of 1,2,3 and 4 mm in conical diameters of 3.0, 3.5, and 4.3 | Angled Multi-Unit Abutments 18° and 30° in heights of 1,2,34 and 5 mm | | Dentsply Sirona K163350 Multibase Abutments EV 2-piece abutments with threaded cap 3.6, 4.2, 4.8 mm diameter in 17° and 30° cuff heights of 1.5, 2.5 mm |
| **Healing Caps 4.5 diameter** | IH Slim healing cap 4.5 x 8.2, 9.2, 10.2, 11.2, 12.2mm total heights Cuff heights 3.17, 4.17, 5.17, 6.17, 7.17mm and IH Slim healing cap 4.5 with total heights 9.05 or 10.05mm | RP 4.3mm diameter healing cap in 2,3,4,5,6 and 7mm height with total heights of 7.4, 8.3, 9.3, 10.3, 11.3, 12.3 mm<br><br>Hex 4.3mm diameter healing cap in 2,3,4,5,6mm cuff heights total heights 6.7, 7.7, 8.7, 9.7, 10.7, 11.7 mm | Healing Cap Abutments 4.6mm in 2,3,4,5,6and 7 mm | 4.6mm healing cap cuff heights 2,3,4,5,6,7 mm total heights 6.9, 7.9, 8.9, 9.9, 10.9, 11,9 mm | |

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| **Healing Caps 5.5 diameter IH** | Healing cap 5.5 with total heights of 7.5, 8.1, 9.05,10.05,11.05 mm<br>Concave healing cap 5.5 with total heights of 7.95, 8.95, 9.95, 10.95mm | | Healing Cap Abutments in 5.6mm in 2,3,4,5, and 6mm cuff height | K182293<br>5.5 wide healing cap cuff heights 2,3,4,5,6,7 mm and total heights 7.1, 8.1, 9.1, 10.1, 11.1, 12.1 mm | |
| **Healing Caps extra slim 3.50 diameter IH** | Extra slim healing cap 3.5 with total heights of 6.9, 7.9, 8.9 mm | | Healing Cap Abutments in 3.8mm in 2,3,4,5,6,and 7 mm cuff heights | | |
| **Healing Cap narrow emergence 3.6mm conical NP & RP** | Healing cap NP & RP 3.6 with total heights of 8.3, 10.3, 12.3 mm & heights above platform of 2.95, 4.95, 6.95 mm | | NP Healing Cap Abutments in 3.8mm in 2,3,4,5,6,and 7 mm cuff height | 3.8mm healing cap cuff heights 3,4,5,6,7 mm total heights 7.85, 8.85, 9.85, 10.85, 11.85 mm | |
| **Healing Cap 5.0 conical NP & RP** | Healing cap NP & RP 5.0 with total heights of 8.3, 10.3, 12.3mm & heights above platform of 2.95, 4.95, 6.95 NP or 2.8, 4.8, 6.8mm RP | Healing cap conical RP 5.0 with total heights of 8.3, 9.3, 10.3, 11.3, 12.3 mm | | 5.5mm healing cap cuff heights 2,3,4,5,6,7 mm total heights 7.1, 8.1, 9.1, 10.1, 11.1, 12.1 mm | |
| **Healing Cap Wide 6.3mm IH** | Healing cap wide IH 6,3 with total heights of 8, 9, 9.6 mm | Wide emergence Hex healing cap 6.3 in total heights of 6.7, 7.7, 8.7, 9.7, 10.7, 11.7 mm | | 6.3mm healing cap Cuff heights 2,3,4,5 mm total heights 6.85, 7.85, 8.85, 9.85 mm | |
| **Multi-Unit Healing Cap** | Multi-unit healing cap for all connections IH, NP and RP | Single size healing cap for multi-unit | Single size healing cap for multi-unit | | |
| **Straight Anatomic Abutment** | IH anatomic abutments cuff heights 1,2,3,3.7 mm total | IH Anatomic straight abutment | Straight anatomic abutments | | AB Dental Implants K132125 |

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| **in IH NP RP** | heights 11, 12, 13, 14 mm<br><br>IH Straight shoulder abutments cuff heights 1.15,2.15,3 mm total heights 11, 12, 13 mm<br><br>IH straight curve concave abutments Cuff heights 1,2,3,4 mm total heights 11, 12, 13, 14 mm<br><br>NP 3.0<br>RP 5.0<br>Cuff heights 1.48/1.4, 2.9 mm<br>Total heights NP & RP 10.3, 11.8 mm | with cuff heights of 1,2,3 mm total heights of 9.5, 10.5, 11.5 mm | in cuff heights 1,2,3,4 mm total heights 9, 10, 11, 12 mm<br><br>Straight flat-sided abutment 4.5mm diameter total heights of 5, 7, 9, 11, 13, 15mm | | P3 and P3-5 Hex Standard Titanium Abutment with height of 5,7, 9,11,12,15mm |
| **Straight Wide Anatomic Abutment IH** | 4.5mm cuff heights 1,2,2.7 mm<br>Total heights 11, 12, 13 mm | Conical WP 4.3mm cuff heights 1,2,3 mm total heights 10.2, 11.2, 12.2 mm | Straight flat-sided abutment 4.5mm diameter total heights of 5, 7, 9, 11, 13, 15mm | | Osstem K161604 Abutment for ultra-wide fixtures |
| **Angled Abutment 15°** | 15° Smooth Abutment 3.75mm<br>Total heights 9, 11, 13.5 mm<br><br>15° Smooth thin 3.75mm abutment total height 11 mm<br><br>15° Smooth wide abutment 4.5mm total height 11 mm | Standard 15° abutment with total heights 9,11, 13 mm | Angulated 15°<br>Abutment 9, 13 mm | | |
| **Angled Abutment 25°** | 25° smooth abutment 3.75mm total heights 9.5, 11, 13.5mm | 25° non-shouldered | | | |

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| | | abutments 3.75mm total heights 9, 11, 13mm | | | |
| **Angled 15° Abutment with cuff in IH NP RP** | IH 3.75mm concave curve 15° abutment with cuff heights 1.05,2,3,4 mm total heights 11, 12, 13, 14 mm<br><br>NP 4.2mm<br>RP 5.0mm<br>Cuff heights 1.5, 3.0/2.9 mm<br>Total heights NP & RP 10.3, 11.8 mm<br><br>IH 3.75mm 15° Anatomic Abutment cuff height 1,1.9,3, 3.7mm<br>Total heights 11, 12, 12.5, 13.7 mm | Anatomic shouldered 15°abutment cuff heights 1,2,3 mm total heights 9.53, 10.53, 11.53 mm | Anatomic 15° Angulated Abutment with collar Heights of 1,2,3,4 mm Total heights 9.5, 10.5, 11.5, 12.5 mm | 15°shouldered abutment cuff heights 1,2,3 mm total heights 10.99, 12, 12.97 mm | AB Dental K132125 Hex RP P4 15° Abutment with height of 8,9mm Hex RP P4L 15° Abutment height of 13.4mm Conical RP 15° Abutment P4C height of 9mm<br><br>AB Dental Implants K132125 P3 and P3-5 Hex Standard Titanium Abutment with height of 5,7, 9,11,12,15mm |
| **Angled 25° Abutment with cuff in IH** | IH 3.75mm concave curve 25° abutment with cuff heights 1,2,3,4 mm total heights 11, 12, 13, 14 mm<br><br>IH 3.75mm 25° Anatomic Abutment cuff height 1,2,3, 4 mm Total heights 11, 12, 12.8, 13.5 mm<br><br>IH 4.5mm 25° wide anatomic abutment cuff height 1, 2, 2.7mm | Anatomic shouldered 25°abutment cuff heights 1,2,3 mm total heights 9.53, 10.53, 11.53 mm | Anatomic Angulated Abutment 25° with collar heights of 1,2,3,4mm Total heights 9.5, 10.5, 11.5, 12.5 mm | 25° shouldered abutment cuff heights 1,2,3 mm total heights 11.3, 12.2, 13.2 mm | AB Dental K132125 Hex RP P4 25° Abutment with height of 8,9mm Hex RP P4L 25° Abutment height of 13.4mm Conical RP 25° Abutment P4C height of 9mm<br><br>AB Dental Implants K132125 |

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| | Total heights 11, 12, 13mm | | | | P3 and P3-5 Hex Standard Titanium Abutment with height of 5,7, 9,11,12,15mm |
| **Wide 15° Abutment with cuff in IH** | 4.5mm diameter IH anatomic abutment<br>Cuff heights 1.25, 2 mm<br>Total heights 11, 12 mm | Anatomic 4.3 wide platform 15° abutment cuff heights 1,2, or 3mm total heights 10.23, 11.23, 12.23 mm | Anatomic angled 15° abutments cuff heights 1,2,3,4 mm total heights 9.5, 10.5, 11.5, 12.5 mm | | Osstem K161604 Angled 15° abutment for ultra-wide fixtures |

**Conclusion:**

Surcam Dental Implant System is substantially equivalent to Surgikor Dental Implant System. They both have the same indications for use, are of the same material, and have internal hex or conical connections. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Any abutment designs not found within the Surgikor Dental Implant System were found in the reference devices which have the same materials, similar indications for use and same internal hex or conical connections as the Surcam Dental Implant System. Performance testing demonstrates substantial equivalence to the identified predicate devices.