July 8, 2019

Surgikor LLC
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K182615
Trade/Device Name: Surgikor Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 3, 2019
Received: April 9, 2019

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 (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,

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182615

Device Name
Surgikor Dental Implant System

Indications for Use *(Describe)*
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 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 7mm implants are intended to be used in the molar region.

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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510k Summary
K182615
July 8, 2019
Surgikor Dental Implant System

Name and address of Submitter: Surgikor LLC
1299 W Jefferson Blvd
Los Angeles CA, 90007
Contact Person: Jeremy Barbanell
Phone Number: +1 562-714-9732
Name of device: Surgikor Dental Implant System
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA

Device Description: The Surgikor Dental Implant System consists of two stage endosseous form dental implants, hexagonal and conical implants and hexagonal and conical abutments; cover screws and healing caps; abutment systems including multi-unit abutments. Implants and abutments are made from Ti6AL4V ELI.

The Surgikor Dental Implant System includes:

Versatile model is a platform switched, tapered implant designed for use in any bone type and is offered with a Morse tapered hex connection. The regular hex platform comes in diameters of 3.5, 3.75, 4.2, 4.5, 5.0 and 6.0mm. Lengths of 8, 10, 11.5, 13 and 16 are available with 18 and 20 mm lengths available in the 4.2 diameter only.

Immediate model is a platform switched root-form implant design. The Immediate suitable for both immediate load applications and insertion into fresh extraction sockets and is offered with a Morse tapered hex connection in regular platform. It is available in 3.75, 4.2, 4.5, 5.0, 6.0, and 7.0 mm diameter. The hex is regular platform and comes in lengths of 7 (4.5, 5, 6.and 7mm only), 8, 10, 11.5, 13, 16 (7.0mm diameter not in 11.5,13 or 16 mm length).

Fixation model is a root form implant is appropriate for both immediate load applications and insertion into fresh extraction sockets. The Fixation is offered with a conical connection in narrow, regular and wide platforms. The 3.0 diameter implant is available in narrow platform and lengths of 10, 11.5, 13 and 15mm. The Fixation regular platform implant is available in 3.5 and 3.9 mm diameter and has available lengths of 8.5, 10, 11.5, 13, 15, and 18 mm. Wide platform is available in 4.3 and 5.0 mm diameter with lengths of 8.5, 10, 11.5, 13, 15 and 18mm.

Solution model is equipped with a specially designed, narrow, deep, conical connection and is designed for use in narrow bone volumes. The Solution5 is available in narrow platform with a

diameter of 3.25mm and lengths of 10, 11.5, 13, 15 mm. The regular platform is available in 3.5, and 4.0 diameter in lengths of 7.0 (4.0 diameter only), 8.5, 10. 11.5, 13, 15mm. The wide platform is available in diameters of 4.5, 5.0, 5.5 and 6.0mm. These diameters come in lengths of 7.0, 8.5, 10, 11.5, 13, and 15mm. The Solution2 is available with lengths of 10, 11.5, 13, and 16 mm in a diameter of 3.25 mm. The Solution5 and Solution2 differ in that the Solution5 implants have an outer thread like the Versatile model, while the Solution2 have an outer thread like the Immediate model.

Healing caps are available in 3 platform sizes: normal, narrow and wide. The conical connection models are available in narrow, regular and wide platforms with lengths of 2, 3, 4, 5, 6, 7 mm and diameters of 3.0, 3.5 and 4.3 mm. There is also a wide platform conical connection healing cap for both narrow emergence and wide emergence. These are 4.3 mm diameter in lengths of 2, 3, 4, 5, 6 and 7 mm. The hex connection models are available in narrow emergence, regular platform with lengths of 2, 3, 4, 5, 6, 7 mm and a diameter of 3.75 mm and standard & wide emergence regular platform with lengths of 2,3, 4, 5, and 6 mm and a diameter of 3.75 mm. There is also a healing cap for the multi-unit abutment which comes in one size. Healing caps with marks for scanning are available in 2mm length for regular hex, narrow conical, regular conical and wide conical platforms.

Temporary abutment is for immediate loading if appropriate. The Temporary abutment is available with a conical connection in narrow, regular and wide platforms all with lengths of 1, 2, 3, 4, 5, 6 and 7 mm and diameters of 3.0, 3.5 and 4.3 mm. It is also available with a hex connection regular platform with lengths of 1, 2, 3, 4, 5, 6, 7 mm and a diameter of 3.75 mm.

Non-shouldered abutments are straight titanium abutments with hex designed for permanent restoration. The abutments are supplied as regular non-shouldered straight abutments with lengths of 5, 7, 9, 12 and 15 (not in narrow conical) mm with a narrow conical platform of 3.0 mm width, a regular conical platform of 3.5 mm width, a wide conical platform of 4.3mm and with a regular hex platform of 3.75 mm width. Also available is a wide emergence non-shouldered straight abutment with lengths of 5, 7, 9, 12 and 15 mm with a wide conical platform of 4.3 mm. The 5mm height non-shouldered abutments are intended for multiple unit restorations only.

15° and 25°angular non-shouldered abutments: 15° abutments are supplied in lengths of 9, 11 and 13 mm with either a hex connection (3.75mm) or a conical connection in narrow (3.0mm), regular (3.5mm) or wide (4.3mm) platform. 25° abutments are supplied in lengths of 9, 11 and 13 mm with a hex connection, a conical connection regular platform or a conical connection wide platform. 15° and 25° narrow emergence abutments are supplied as a hex connection regular platform with a width of 3.75 mm. 15° and 25° wide emergence abutments are supplied as a wide platform conical connection with a width of 4.3 mm and lengths of 9, 11, and 13mm.

Anatomic Straight Shouldered Abutments All have a length of 7.5mm and shoulder heights of 1, 2 and 3 mm. They are available in the following configurations: conical connection, narrow, regular or wide platform or hex connection regular platform. Wide emergence versions are available in wide conical connection and regular hex connection.

15˚, and 25˚ Angled Anatomic Abutment with Shoulder, all have a length of 7.5 mm and shoulder heights of 1, 2 and 3 mm. They are available in conical connection, narrow (available in 15° only),

regular and wide platform and hex connection regular platform. Wide emergence version are available in wide conical.

Ball Attachment Abutments are provided with lengths of 1, 2, 3, 4, 5, and 6 mm and in the following configurations: Conical connection, narrow platform 3.0 mm diameter, Conical connection, regular platform 3.5 mm diameter, Conical connection, wide platform 4.3 mm diameter , Hex connection, regular platform 3.75 mm diameter. Ball attachment abutments are intended for multiple unit restorations only.

Multi-Unit Abutment are supplied with lengths of 1, 2, 3 and 4 mm. They are available in narrow regular and wide conical platforms and in hex regular platform. An angled multi-unit of either 18° or 30° is available for conical connections of narrow, regular and wide platform. A plastic sleeve for casting an extension for using multi-units in single units is included in the 510k. Multi-unit abutments are intended for multiple unit restorations only.

Standard Locator Abutments are supplied in shoulder heights of 1, 2, 3, 4, 5, and 6mm. Locators are intended for multiple unit restorations only.

Castable abutments are available in hexed and non-hexed in hex or conical connection (all three platforms). They are available in Ti alloy and gold. A plastic sleeve is available for use with the castable abutments. They are intended for casting straight abutments taller than 4mm.

Abutment Screws are available for hex connection and for all three platforms of conical connection.

Cover Screw are supplied with a conical connection as narrow, regular and wide and with a hex connection.

Indications for Use: 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 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 7mm implants are intended to be used in the molar region.

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. The gold used for UCLA abutments was shown to be biocompatible. The CoCr used for castable abutments was shown to be biocompatible. 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.

Primary Predicate: Cortex Dental Implants K163385
Reference Devices: Cortex Dental Implants K090709 AB Dental Implants K132125 & K181381 and Osstem K161604

Substantial Equivalence:

Surgikor's Dental Implant System is substantially equivalent to Cortex 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 Osstem reference devices are used for demonstrating equivalence in device design and size for larger implants and abutments. The Osstem wider implants also have the indications limitation for only use in the molar region. 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 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	Surgikor's Dental Implant System	Cortex Dental Implants K090709 and K163385	AB Dental Implants K132125 & K181381	Osstem K161604
Indications for Use	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 patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is	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 function. The system is intended to be used in either single teeth or	**A.BDENTAL DEVICES®** Dental Implants 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. A.B. **DENTAL DEVICES®** Dental Implants	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.

	achieved and with appropriate occlusal loading. The 7mm implants are intended to be used in the molar region.	multiple teeth applications.	System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. 'Two Stage Implants: **12,15,1661.** One Stage: **16, 16b,** 16B.One Stage **&** One-Piece **3.0** mm diameter implants: **16,** 168, 1681, are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. One stage **&** One-Piece 2.4 mm diameter implants for temporary use or long term use: **16, 16b,** permit immediate	

			splint stability and long term fixation of new or existing crown, bridge and prosthesis. P14 Angulated Abutment Adapter is to be used with implant diameter 4.2mm and higher.	
Implant Diameters	Versatile Hex 3.5, 3.75, 4.2, 4.5, 5.0, 6.0mm Immediate Hex 3.5, 3.75,4.2, 4.5, 5.0, 6.0, 7.0mm Fixation Narrow Platform 3.0mm Fixation Regular Platform 3.5, 3.9mm Fixation Wide Platform 4.3, 5.0mm Solution5 Narrow Platform 3.25mm Solution5 Regular	Classix 3.3, 3.8, 4.2, 5.0, 6.0 Conical and Hex Dynamix 3.0, 3.3, 3.8, 4.2, 5.0, 6.0 Conical and Hex Saturn 3.8, 4.2 Hex 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

	Platform 3.5, 4.0mm Solution5 Wide Platform 4.5, 5.0, 5.5, 6.0mm Solution2 3.25mm			
Implant Lengths	Versatile Hex 8, 10, 11.5, 13, 16, 18 (4.2 only), 20 (4.2 only)mm Immediate Hex 8 (no 3.5 diameter) 10, 11.5, 13, 16mm 7.00 diameter not in 11.5, 13 or 16mm. Fixation Narrow Platform 10, 11.5, 13, 15mm Fixation Regular Platform 8.5, 10, 11.5, 13, 15, 18mm Fixation Wide Platform 8.5, 10, 11.5, 13, 15, 18mm Solution5 Narrow Platform 10,11.5, 13, 15mm Solution5 Regular Platform 7.0 (4.0 diameter	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 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 Saturn 8,10,11.5,13,16 Magix 8,10,11.5,13 no 3.3 in 8		Osstem 6.2,7.0,8.5,10,11.5,13,15,18

	only), 8.5, 10, 11.5, 13, 15mm Solution5 Wide Platform 7.0, 8.5, 10, 11.5, 13, 15mm Solution2 10, 11.5,13 16mm			
Material of devices included in the submission	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Type of abutment and maximum angulation	Pre-manufactured of no more than 25°	Pre-manufactured of no more than 25°	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	Internal hex
ISO 14801 Fatigue Testing	Sufficient run out load for their intended use	Sufficient run out load for their intended use	Sufficient run out load for their intended use	Sufficient run out load for their intended use
Surface Treatment	HA blasted and double acid etched	Alumina blasted and acid etched	HA blasted	Sand blasted and acid etched
Post Surface Treatment Cleanliness Demonstrated	Yes	Yes	Yes	Yes

Cover screw	Cover screw	Cover screw		
Multi-Unit Abutments in Hex RP and Conical (NP,RP,WP)	Multi-unit abutments in heights of 1,2,3 and 4 mm in conical diameters of 3.0, 3.5, and 4.3 plus hex diameter of 3.75	Straight Multi-unit Abutments in heights of 1,2,3,4 and 5 mm		
18° and 30 °Angled Multi-Unit	Multi-unit abutments in heights of 1,2,3 and	Angled Multi-Unit Abutments 18° and		

Abutments in Conical (NP,RP,WP)	4 mm in conical diameters of 3.0, 3.5, and 4.3	30° in heights of 1,2,34 and 5 mm		
Locator Abutments in Hex RP	Locator abutments in heights of 1,2,3,4,5,and 6mm	Low Profile Abutments 5.5mm and 7mm in height of 9mm	AB Dental K132125 P25 AB Lock in heights of 0, 1,2,3,4 and 5 mm	
Ball attachments in Hex RP and Conical NP,RP.WP	Ball attachments in heights of 1,2,3,4,5, and 6mm	Ball Attachment System in heights of 1,2,3,4,5,6 and 7mm		
Healing Caps 4.5 diameter standard	Conical healing cap in 2,3,4,5,6 and 7mm height Hex healing cap in 2,3,4,5,6mm height	Healing Cap Abutments 4.6mm in 2,3,4,5,6and 7 mm		
Healing Caps 5.5 diameter wide	Conical healing cap in 2,3,4,5,6 and 7mm height	Healing Cap Abutments in 5.6mm in 2,3,4,5, and 6mm height		
Healing Caps 3.75 diameter narrow	Conical healing cap in 2,3,4,5,6 and 7mm height	Healing Cap Abutments in 3.8mm in 2,3,4,5,6,and 7 mm height		
Healing Cap narrow emergence conical WP and Hex RP	Narrow emergence hex and wide conical healing cap in 2,3,4,5,6 and 7 mm height		AB Dental K132125 PON narrow emergence healing cap in 3,4,5,6 and 7mm height	
Healing Cap wide emergence conical WP	Wide emergence wide conical healing cap in 2,3,4,5,6 and 7 mm height Wide emergence Hex healing cap in 2,3,4,5,6mm height			Osstem K161604 Healing Cap for ultra-wide fixtures
Multi-Unit Healing Cap	Single size healing cap for multi-unit	Single size healing cap for multi-unit		
Standard Titanium Abutment Hex RP Conical RP and WP	Non-shouldered Standard Titanium Abutment with heights of 5,7, 9, 12, and 15 mm in Hex	Ttianium abutments in 7.5 and 9mm height	AB Dental Implants K132125 P3 and P3-5 Hex Standard	

	RP, Conical RP and WP		Titanium Abutment with height of 5,7, 9,11,12,15mm P3C Conical Standard Titanium Abutment height of 9mm	
Standard Narrow Abutment in Conical NP	Non-shouldered Standard narrow abutment with heights of 5,7,9 and 12 mm in Conical NP	Ttianium abutments in 7.5 and 9mm height		
Standard Wide Emergence Abutment in Conical WP	Non-shouldered standard wide emergence abutment with heights of 5,7,9,12, and 15mm			Osstem K161604 Abutment for ultra-wide fixtures
Standard Shoulder Abutment	Standard shoulder abutment in heights of 1,3 and 4mm	Straight Abutment with collar in heights of 1,2,3 and 4mm		
Standard Wide Shoulder Abutment	Standard Wide Shoulder Abutment with heights of 1,2,3,and 4mm	Standard Wide Shoulder Abutment with heights of 1,2,3,and 4mm		
Standard 15° Abutment in Hex RP and Conical NP, RP, WP	Standard 15° Abutment with lengths of 9,11,13mm	Angulated 15° Abutment 9,12mm	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	
Standard 25° Abutment in Hex RP and Conical RP, WP	Standard 25° Abutment with lengths of 9,11,13mm	Angulated 25° Abutment 9,12mm	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	
Narrow Emergence Standard 15° Abutment in Hex RP	Lengths of 9,11,13mm	Angled 15° Abutment Slim 9mm	AB Dental K132125 Hex RP P4N 15° Narrow Abutment height 9mm	
Narrow Emergence Standard 25° Abutment in Hex RP	Lengths of 9,11,13mm	Angled 25° Abutment Slim 9mm		
Wide Emergence Standard 15° Abutment in Conical WP	Lengths of 9,11,13mm		AB Dental K132125 Hex RP P4ST 15° Abutment height of 9mm P4-5 15° Abutment height of 10.75, 11.1mm	
Wide Emergence Standard 25° Abutment in Conical WP	Lengths of 9,11,13mm		AB Dental K132125 Hex RP P4ST 25° Abutment height of 9mm P4-5 25° Abutment height of 10.75, 11.1mm	
Anatomic Shouldered Standard 15° Abutment Hex RP Conical NP.RP and WP	Heights of 1,2, or 3mm	Anatomic 15° Angulated Abutment with collar Heights of 1,2,3,4 mm	AB Dental K132125 Hex RP 15° Shouldered Abutment of height 1,2 3mm overall height of 7	
Anatomic Shouldered Standard 25°	Heights of 1,2, or 3mm	Anatomic Angulated Abutment 25° with collar		

Abutment Hex RP Conical RP and WP		Heights of 1,2,3,4mm		
Wide Emergence Anatomic Shouldered Standard 15° Abutment	Heights of 1,2, or 3mm			Osstem K161604 Angled 15° abutment for ultra-wide fixtures
Wide Emergence Anatomic Shouldered Standard 25° Abutment	Heights of 1,2, or 3mm			Osstem 161604 Angled 25° abutment for ultra-wide fixtures
UCLA in Ti	4.5mm hexed and non-hexed in NP,RP,WP and RH	4.5 mm castable abutments		
UCLA in Gold	4.5mm hexed and non-hexed in NP,RP,WP and RH	4.5 mm castable abutments		

Conclusion:

Surgikor Dental Implant System is substantially equivalent to Cortex Dental Implant System. They both have the same indications for use, are of the same material, and have internal hex or conical connections. The predicate device system does not have 7mm implants so does not have the indications statement about them being used in the molar region. The 7mm implants have the same indications limitation as the reference devices from Osstem which are wider implants. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Any abutment designs not found within the Cortex 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 Surgikor Dental Implant System. Performance testing demonstrates substantial equivalence to the identified predicate devices.