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

September 12, 2024

Re: K240803
Trade/Device Name: Surgikor Fixation One, Abutment Blanks and Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 20, 2024
Received: August 22, 2024

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.

Submission Number *(if known)*

K240803

Device Name

Surgikor Fixation One, Abutment Blanks and Abutments

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.

Surgikor Abutment Blanks and Abutments are intended to be used in conjunction with Surgikor 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 Surgikor Abutment Blanks are intended to be sent to a Surgikor validated milling center for manufacture.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K240803 510k Summary
September 10, 2024
Surgikor Fixation One, Abutment Blanks and Abutments

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 Fixation One, Abutment Blanks and Abutments
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Product Code: DZE, NHA

Submission Contact:
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Primary Predicate Device: Surgikor Dental Implant System K182615
Predicate/Reference Devices: Blue Sky Bio Cad CAM Abutments K202026, Nobel Biocare Multi-Unit Plus K161416 (for conical straight and angled multi-units), Cortex K090709, & K163385 (for healing cap size) Blue Sky Bio BioMax and Bio Internal Hex K102034 (implant sizes and platforms)

Device Description: The Surgikor Fixation One implant is an alternative version of the 4.3 and 5.0 mm diameter Fixation implants that uses the regular platform used by the 3.5mm Fixation implants. The Surgikor abutment blanks and abutments consist of hexagonal and conical abutments made from abutment blanks, an additional hexagonal healing cap, and multi-unit abutments for conical RP and WP. Surgikor implants and abutments are made from Ti6AL4V ELI.

Fixation One is a root form implant that is appropriate for both immediate load applications and insertion into fresh extraction sockets. Fixation One is offered with a conical connection

in regular platform. The Fixation One regular platform implant is available in 4.3, and 5.0 mm diameter and has available lengths of 8.5, 10, 11.5, 13, 15, and 18 mm.

Healing cap for internal hex in 3.75mm x 7mm in standard emergence.

Multi-Unit Abutment in conical RP and WP are available in heights of 1.5, 2.5, and 3.5 mm. An angled multi-unit of either 17° (2.5 or 3.5 mm) or 30° (3.5 or 4.5 mm) is available for conical connections of regular and wide platform. Multi-unit abutments are intended for multiple unit restorations only. Angled multi-units use RP and WP conical multi-unit screws.

Surgikor Blank Abutments are designed for fabrication of a customized all titanium alloy abutment by CAD-CAM processes. Surgikor Blank Abutments have an engaging implant connection. Abutments made from Surgikor Blank Abutments use internal hex abutment screws and RP & WP conical abutment screws from K182615.

The design parameters for customized abutments fabricated from Titanium Blank Abutments are:
Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restorations (length above the abutment collar / gingival height)– 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.7 mm
Maximum angulation – 25° (in relation to the long axis of the implant)

All abutment blanks are made of titanium alloy conforming to ASTM F136. Abutments made from the blanks are only for use with Surgikor dental implants of the implant/abutment interface on the package label and are not to be used with other dental implant designs. This includes Versatile Hex 3.5mm and larger, Immediate Hex 3.75mm and larger, and Solution Fixation & Fixation One conical 3.5mm and larger.

There are 3 models of abutment blank: internal hex, conical RP and conical WP.

Minimum diameter at abutment/implant interface:
Versatile Hex 3.5mm
Immediate Hex 3.75mm
Solution 3.5mm
Fixation 3.5mm
Fixation One 4.3mm

Maximum length of abutment from abutment/implant interface:
Versatile and Immediate Hex 13.00mm
Solution 9.5mm
Fixation and Fixation One 9mm

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.

Surgikor Abutment Blanks and Abutments are intended to be used in conjunction with Surgikor 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 Surgikor Abutment Blanks are intended to be sent to a Surgikor validated milling center for manufacture.

Testing Summary: Cytotoxicity and steam sterilization validation of the abutments and abutments made from blanks are the same as the predicate device K182615. Gamma irradiation validation, LAL testing, shelf-life, cytotoxicity, surface assessment, and bench testing for the Fixation One implant body is leveraged from K182615.

MR Environment Condition
Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the Surgikor Dental Implant System 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 compositions.
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.

Substantial Equivalence:
Surgikor’s Fixation One implants, Abutment Blanks and Abutments are substantially equivalent to the predicate devices. They have the same indications for use, materials, design, principles of operation and sterilization. The abutment blanks have very similar parameters.

Company & Device Name	Surgikor's Fixation One (Devices in this submission)	Surgikor's Dental Implant System K182615 Primary Predicate Device	Blue Sky Bio CAD CAM Abutments K202026 (With additional implant information from K102034)
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. Surgikor Abutment Blanks and Abutments are intended to be used in conjunction with Surgikor 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 Surgikor Abutment Blanks are intended to be sent to a Surgikor validated milling center for manufacture.	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. (Note that 7mm implants have been removed from sale so this statement in the indications is no longer needed)	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.
Materials	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Principle of Operation	Abutments and CAD/CAM abutments made from blanks for	Abutments for the restoration of dental implants.	Abutments and CAD/CAM abutments made from blanks for

	the restoration of dental implants. Dental implants for replacement of lost teeth to restore chewing function.	Dental implants for replacement of lost teeth to restore chewing function.	the restoration of dental implants.
Implant diameters and lengths in this submission	Fixation One 4.3 & 5.0 mm diameter in lengths of 8.5, 10, 11.5, 13, 15, 18mm	Fixation 4.3 & 5.0 mm diameter in lengths of 8.5, 10, 11.5, 13, 15, 18mm	Biomax implants 4.3 & 5.0 mm diameter in lengths of 6,8,10,11,and 13mm
Implant connection in this submission	RP conical	WP Conical	RP conical

	Surgikor's, Abutment Blanks (Devices in this submission)	Blue Sky Bio CAD CAM Abutments K202026 (With additional implant information from K102034)
Abutments made from abutment blanks fit Implant design of the manufacturer	Yes	Yes
Interface type/shape	Internal hex, conical	Internal hex, conical
Location of Manufacturer of Abutments from the Abutment Blanks	Surgikor validated milling center	Blue Sky Bio validated milling center
Parameters for Making Abutments from Abutment Blanks	Surgikor Blank Abutments are designed for fabrication of a customized all titanium alloy abutment by CAD-CAM processes. Surgikor Blank Abutments have an engaging implant connection. The design parameters for customized abutments fabricated	Titanium Blank Abutments are designed for fabrication of a customized all titanium alloy abutment by CAD-CAM processes. Titanium Blank Abutments have an engaging implant connection. The design parameters for customized abutments fabricated from Titanium Blank Abutments are:

	from Titanium Blank Abutments are: Minimum wall thickness – 0.4 mm Minimum post height for single-unit restorations – 4.0 mm Minimum gingival height – 0.5 mm Maximum gingival height – 6.7 mm Maximum angulation – 25° (in relation to the long axis of the implant)	Minimum wall thickness – 0.4 mm Minimum post height for single-unit restorations – 4.0 mm Minimum gingival height – 0.5 mm Maximum gingival height – 6.7 mm Maximum angulation – 30°
Abutment design parameters based on fatigue testing parameters	Yes	Yes
Implant bodies used with abutment blanks Minimum diameter of implant given.	Internal Hex Versatile Hex 3.5mm Immediate Hex 3.75mm RP&WP Conical Solution 3.5mm Fixation 3.5mm Fixation One 4.3mm	Internal Hex Bio Internal Hex 3.7mm Conical BioMax NP 3.0mm BioMax RP 4.3mm

	Additional Surgikor Dental Implant System Devices	Cortex K090709 & K163385
Healing Caps Standard Emergence 3.75mm	3.75 x 7mm healing cap standard emergence	3.8 x 7mm healing cap

	Additional Surgikor Dental Implant System Devices	Nobel Biocare Multi-Unit Plus K161416

Conical Multi-Unit Abutment RP	Conical RP Multi-Unit in gingival heights of 1.5/2.5/3.5 mm	Conical RP Multi-Units in gingival heights of 1.5/2.5/3.5/4.5 mm
Conical Multi-Unit Abutment WP	Conical WP Multi-Unit in gingival heights of 1.5/2.5/3.5 mm	Conical WP Multi-Units in gingival heights of 1.5/2.5/3.5/4.5 mm
Conical Multi-Unit Abutment 17° RP	Conical RP 17° Multi-Unit in gingival heights of 2.5/3.5 mm	Conical RP 17° Multi-Units in gingival heights of 1.5/2.5/3.5/4.5 mm
Conical Multi-Unit Abutment 17° WP	Conical WP 17° Multi-Unit in gingival heights of 2.5/3.5 mm	Conical WP 17° Multi-Units in gingival heights of 1.5/2.5/3.5/4.5 mm
Conical Multi-Unit Abutment 30° RP	Conical RP 30° Multi-Unit in gingival heights of 3.5/4.5 mm	Conical RP 30° Multi-Units in gingival heights of 1.5/2.5/3.5/4.5 mm
Conical Multi-Unit Abutment 30° WP	Conical WP 17° Multi-Unit in gingival heights of 3.5/4.5 mm	Conical WP 30° Multi-Units in gingival heights of 1.5/2.5/3.5/4.5 mm

Conclusion:

Surgikor Fixation One implants are substantially equivalent to the Surgikor Fixation implants. They have the same indications for use, materials, design, principles of operation and sterilization. The 7mm implants have been withdrawn from sale so the restriction on those in the indications is no longer needed. Surgikor Abutment Blanks and Abutments are substantially equivalent to the Blue Sky Bio CAD CAM Abutments. They have the same indications for use, materials, design, principles of operation and sterilization. Parameters for abutments made from abutment blanks are very similar. Abutments made from abutment blanks are manufactured in a validated milling center for both the predicate and subject devices. Abutments made from abutment blanks fit implant bodies the same size and similar connections as those found in the predicate submission. The new abutment designs are all very similar to the reference devices and come in the same range of diameters and gingival heights.