



December 21, 2023

Sky Surgical LLC
% Danielle Besal
Principal Consultant
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K233154

Trade/Device Name: SkyOPS™ Orthopedic Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 27, 2023
Received: September 27, 2023

Dear Danielle Besal:

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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.

Assistant Director

DHT6C: Division of Restorative, Repair
and Trauma Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233154

Device Name

SkyOPS™ Orthopedic Plate System

Indications for Use (Describe)

The SkyOPS™ Orthopedic Plate System is indicated to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments of the foot. The system can be used in both adult and pediatric patients aged >12 years (adolescent, transitional adolescent B).

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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510(k) Summary
SkyOPS™ Orthopedic Plate System
December 21, 2023

Company: Sky Surgical
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Sandpoint, ID 83864

Primary Contact: Danielle Besal
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Company Contact: Jeff Sander
Chief Operating Officer | Sky Surgical
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jsander@sky-surgical.com

Trade Name: SkyOPS™ Orthopedic Plate System
Common Name: Plate, Fixation, Bone; Screw, Fixation, Bone
Classification: Class II
Regulation Number: 21 CFR 888.3030 (Primary) Single/multiple component metallic bone fixation appliances and accessories; 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener

Panel: Orthopedic
Product Code: HRS (Primary), HWC
Predicate Devices: K121437 Mini MaxLock Extreme Plating System (Primary)
K170214 Additive Orthopaedics Locking Lattice Plate
K010321 Modular Foot System – 2.7mm Module
K221181 TMC Plating System

Device Description:

The subject SkyOPS™ Orthopedic Plate System consists of various plates and screws that are used to stabilize and aid in the fusion or repair of fractures or osteotomies of small bones. The plates are offered in different lengths and sizes. The screws are offered in one diameter with different lengths. All implantable metal components are made from Ti-6Al-4V ELI per ASTM F136 or ASTM F3001. The devices are provided non-sterile to be cleaned and steam sterilized by the end user.

Indications for Use:

The SkyOPS™ Orthopedic Plate System is indicated to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments of the foot. The system can be used in both adult and pediatric patients aged > 12 years (adolescent, transitional adolescent B).

Substantial Equivalence:

The SkyOPS™ Orthopedic Plate System is substantially equivalent to the predicate devices (K121437, K170214, K010321, K221181). The subject and predicate devices are identical in intended use and materials and equivalent in technological characteristics. Testing has demonstrated that performance of

the subject devices is equivalent to that of the predicates and, thus, the differences in geometry and manufacturing versus the predicates do not raise different questions of safety and effectiveness.

Performance Testing:

Biocompatibility testing per ISO 10993-1 and performance testing per ASTM F534-17 (Annexes 1-3) and ASTM F384-17 (Annexes 1-2) was conducted on the subject devices and results demonstrated substantial equivalence to the predicates.

Conclusion:

The SkyOPS™ Orthopedic Plate System is considered substantially equivalent to the predicate devices (K121437, K170214, K010321, K221181).