April 19, 2023

Stabiliz Orthopaedics Inc.
% Hollace Rhodes
VP, Orthopedic Regulatory Affairs
MCRA, LLC.
803 7th Street NW
3rd Floor
Washington, District of Columbia 20000-1

Re: K230053
Trade/Device Name: SimpliFix Hip System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 31, 2023
Received: March 31, 2023

Dear Hollace Rhodes:

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,

Shumaya Ali -S

Shumaya Ali, MPH
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230053

Device Name
SimpliFix Hip System

Indications for Use *(Describe)*
The SimpliFix Hip System is intended for fracture fixation of large bones and large bone fragments such as femoral neck fractures, slipped capital femoral epiphyses and an adjunct to a dynamic hip screw (DHS) in basilar neck fractures.

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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K230053
510(k) Summary

Device Trade Name:	SimpliFix Hip System
Manufacturer:	Stabiliz Orthopaedics, Inc. 600 Eagleview Blvd Unit 300 Exton, PA 19341
Contact:	Douglas L. Cerynik, MD President & CEO Stabiliz Orthopaedics, Inc.
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	April 18, 2023
Regulation:	21 CFR 888.3040
Class:	II
Product Codes:	HWC
Primary Predicate:	Synthes 6.5mm Cannulated Screw (K021932)
Additional Predicate:	Smith and Nephew Cannulated Screws and Washers (K111994)
Reference Device:	BioPro Go-EZ Screw (K081149)

Indications For Use:
The SimpliFix Hip System is intended for fracture fixation of large bones and large bone fragments such as femoral neck fractures, slipped capital femoral epiphyses and an adjunct to a dynamic hip screw (DHS) in basilar neck fractures.

Device Description:
The SimpliFix Hip System is designed for angular and rotational stability when used for fracture fixation of large bones and large bone fragments such as femoral neck fractures, slipped capital femoral epiphyses and an adjunct to DHS in basilar neck fractures.

The system is comprised of Cannulated and Cross Screws that are used together to aid fracture fixation.

Discussion of Predicate & Reference Devices:
Stabiliz submits the following information in this premarket notification to demonstrate that, for the purposes of FDA's regulation of medical devices, SimpliFix Hip System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to predicate devices including the Synthes 6.5mm Cannulated Screw (K021932) and Smith and Nephew Cannulated Screws and Washers (K111994). A reference device, BioPro Go-EZ Screw (K081149), was used to support the biocompatibility of the SimpliFix Hip System based on comparable materials and manufacturing processes.

Performance Testing Summary:
The SimpliFix Hip System components have undergone the following testing to establish substantial equivalence to the predicate device.

- Dynamic screw construct testing
- Screw performance testing per ASTM F543
- Screw performance testing per ASTM F1264
- Pyrogenicity testing

Substantial Equivalence:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods.

Conclusion
The data included in this submission demonstrate the SimpliFix Hip System's substantial equivalence to the predicate device. SimpliFix Hip System is as safe, as effective, and performs as well as, or better, than the identified predicate device.