ChoiceSpine, LLC
Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

August 31, 2021

Re: K211449
Trade/Device Name: Triton™ Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: July 29, 2021
Received: July 30, 2021

Dear Kim Finch:

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

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K211449

Device Name
Triton™ Sacroiliac Joint Fixation system

Indications for Use *(Describe)*
The Triton™ Sacroiliac Joint Fixation system is intended for fixation of sacroiliac joint distruptions, and intended for sacroiliac joint fusion for conditions including;
-sacroiliac joint disruptions,
-degenerative sacroilititis
-to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
-Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

☒ 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

Date:	July 7, 2021
Sponsor:	ChoiceSpine, LLC 400 Erin Drive Knoxville, TN 37919
Phone:	865-246-3333
Fax:	865-246-3334
Contact Person:	Kim Finch, Director of Regulatory Affairs
Proposed Proprietary Trade Name:	Triton™ Sacroiliac Joint Fixation System
Product Class:	Class II
Classification Name:	Triton™ Sacroiliac Joint Fixation System • 21 CFR 888.3040- Smooth or Threaded Metallic Bone Fixation Fastener
Device Product Code:	Triton™ Sacroiliac Joint Fixation System • OUR
Purpose of Submission:	The purpose of this submission is to gain clearance for the new Triton™ Sacroiliac Joint Fixation System.
Device Description:	The Triton™ Sacroiliac Joint Fixation System is a multiple component system consisting of non-sterile instruments and sterile, cannulated Ø8mm, Ø12mm and Ø14mm Screws offered in multiple lengths. The Triton SI Screws are manufactured from medical-grade titanium alloy (Ti-6AI-4V ELI) per ASTM F3001, Class C. The implants feature 3 fluted channels for bone collection and a tapered proximal tip. The Ø12mm and Ø14mm Screws feature multiple open and porous-filled windows for packing and disbursement of autograft and allograft materials.
Indications for Use:	The Triton™ Sacroiliac Joint Fixation System is intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including; • sacroiliac joint disruptions • degenerative sacroiliitis • to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and • Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.
Materials:	The Triton™ Sacroiliac Joint Fixation System implants are composed of a titanium alloy (Ti-6Al- 4V ELI per ASTM F3001, Class C). The system instrumentation is made from medical grade stainless steels, aluminum, and

plastics.

Predicate Devices:

Primary Predicate:
Orthofix Firebird SI Fusion System (K203138)
Additional Predicates:
Synthes Ø6.5mm Cannulated Screw (K021932)
Zyga Technology, Inc. SImmetry® Sacroiliac Joint Fusion System (K151818)
ChoiceSpine Hawkeye VBR System (K171686)

Non-clinical Testing:

Static Pull Out per ASTM F543
Static Torsion per ASTM F543
Static Cantilever per ASTM F2193
Dynamic Cantilever per ASTM F2193

Conclusion/Technological Characteristics:

The only difference between the Triton™ Sacroiliac Joint Fixation System and the predicate devices are device geometry. The differences in geometry are not significant and would not adversely affect the use of the product. The Triton™ System is substantially equivalent in material, size offerings, classification, anatomical location, manufacturing and sterilization methods, surgical approach, principle of operation, indications for use, and mechanical testing plan. The system components were assessed in accordance with ISO 10993-1 and found substantially equivalent to the predicate devices.