July 11, 2018

Wright Medical Technology, Inc.
Alayne Melancon
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K180024
Trade/Device Name: SALVATION Midfoot Nail
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 6, 2018
Received: June 8, 2018

Dear Alayne Melancon:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K180024

Device Name
SALVATION Midfoot Reconstruction System - Midfoot Nail Line Extension

Indications for Use *(Describe)*
The SALVATION™ Midfoot Reconstruction System is indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of bones in the foot and ankle including the metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus; specific examples include: intramedullary medial column fusion and lateral column fusion resulting from neuropathic osteoarthropathy (Charcot).

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

In accordance with the Food and Drug Administration rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the SALVATION Midfoot Reconstruction System – Midfoot Nail Line Extension.

(a)(1) MANUFACTURER IDENTIFICATION

Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	December 20, 2017
Contact Person:	Alayne Melancon Regulatory Affairs Specialist Office: (901)290-5986 Fax: (901)867-4190

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name:	SALVATION™ Midfoot Reconstruction System – Midfoot Nail Line Extension
Common Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Classification Name & Reference:	21 CFR 888.3040 – Class II
Device Product Code & Panel:	HWC – Orthopedic

(a)(3) PREDICATE DEVICE INFORMATION

SALVATION Beams and Bolts	K140741

(a)(4) DEVICE DESCRIPTON

The SALVATION Midfoot Reconstruction System, introduced as SALVATION Beams and Bolts in K140741, is being expanded to include the SALVATION Midfoot Nail. Designed to address the demands of advanced midfoot reconstruction, the subject nail features proximal threads and a distal cross screw to ensure fixation and rotational stability.

(a)(5) **INTENDED USE**

The SALVATION™ Midfoot Reconstruction System is indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of bones in the foot and ankle including the metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus; specific examples include: intramedullary medial column fusion and lateral column fusion resulting from neuropathic osteoarthropathy (Charcot).

(a)(6) **TECHNOLOGICAL CHARACTERISTICS COMPARISON**

The subject was designed with the same basic design features (material, geometry, and principle of operation) as the predicate device. A comparison of technological characteristics is shown below in Table 1.

	SUBJECT	PREDICATES
	SALVATION Midfoot Nail	**SALVATION Beams and Bolts System (K140741)**
Material:	Type II Anodized Titanium Alloy per ASTM F136	Type II Anodized Titanium Alloy per ASTM F136
Central Shaft Design:	Cannulated or Solid Core	Cannulated or Solid Core
Size Offerings:	Diameters: 8.0 mm Lengths: 60-160 mm	Diameters: 5.0 mm, 6.5 mm, 7.0 mm Lengths: 50-200 mm

(b)(1) **SUBSTANTIAL EQUIVALENCE – NON-CLINICAL EVIDENCE**

The following evaluations were conducted to support the safety and efficacy of the SALVATION Midfoot Nail:

- Static Bend Testing
- Construct Fatigue Testing
- Pyrogencity Testing

(b)(2) **SUBSTANTIAL EQUIVALENCE – CLINICAL EVIDENCE**
N/A

(b)(3) **SUBSTANTIAL EQUIVALENCE – CONCLUSIONS**

The design characteristics of the subject device do not raise any new types of questions of safety or effectiveness and testing shows no new worst case. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.