Wright Medical Technology, Inc.
Rachel Roberts
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

June 6, 2018

Re: K180832
Trade/Device Name: SALVATION External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: May 10, 2018
Received: May 11, 2018

Dear Rachel Roberts:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

for
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)*

K180832

Device Name
SALVATION External Fixation System

Indications for Use *(Describe)*
The SALVATION External Fixation System is intended for:

• Fusions of the foot including:

o Triple arthrodesis

o Isolated hindfoot arthrodesis

o Midfoot arthrodesis

o Joints involved include tibiotalar, subtalar, talonavicular, calcaneocuboid, pantalar, tibio- talocalcaneus, naviculocuneiform, metatarsal cuneiform (first, second, third – e.g. Lapidus, TMT), metatarsal cuboid

• Treatment of fractures including:

o Treatment of LisFranc fracture/dislocations in diabetic and Charcot neuropathy patient

o Fractures and/or comminuted fractures (open or closed) of the calcaneus, talus, cuboid, navicular, cuneiforms, and/or metatarsals (including Jones fractures), ankle, and distal tibia

o Additional fixation adjunct to internal fixation of the distal tibia, calcaneus, talus, navicular, cuboid, cuneiforms, and/or metatarsals in patients with significant comorbidities (i.e. diabetes) that may preclude use of isolated internal fixation

• Reconstruction of deformities including:

o Neuropathic deformities

o Charcot reconstruction with or without corrective osteotomies

o Diabetic Charcot Reconstruction

o Prevention and treatment of contracture of joints and tendons in equinus

• Treatment of infected unions, nonunions, or malunions

• Offloading and or immobilization of ulcers and/or wounds of the foot or ankle

• Stabilization associated with tendon or ligament surgeries. Tendon lengthening, repairs and transfers both deep and or superficial around the foot and ankle including posterior tibial, tibialis anterior, flexor digitorum longus, achilles, flexor hallucis longus, peroneus brevis, peroneus longus, extensor hallucis longus, extensor digitorum longus

• Tumor and neoplasm resection and reconstruction

• Stabilization associated with rotation flaps, free flaps, muscle flaps, advancement flaps, fasciocutaneous flap, split thickness skin grafting, biological graft alternatives

• Pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction osteogenesis including bone transport

• Correction of bony or soft tissue deformities

• Correction of segmental or nonsegmental bony or soft tissue defects

• Use on long bones including the tibia and fibula

• Use with or without IM nail in the ankle in Charcot patients

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)

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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™ External Fixation System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	March 29, 2018
Contact Person:	Rachel Roberts Regulatory Affairs Specialist Office - (901) 867-9708 Fax - (901) 867-4190
(a)(2). Proprietary Name:	SALVATION External Fixation System
System **Common Name:**	External Fixation Device
Classification Name and Reference:	21 CFR 888.3030 – Class II
Device Product Code, Device Panel:	KTT, Orthopedic
(a)(3). Predicate Device:	K052005: SIDEKICK™ Circular Fixator (formerly R&R External Fixator System) K130044: SIDEKICK™ EZ FRAME Fixator K162033: SALVATION™ External Fixation System

(a)(4). Device Description

The current SALVATION External Fixation System consists of rings, wires, wire fixation bolts, wire posts with bolts, half pins, half pin cubes with bolts, bushings, rocker plates with outsoles, insoles, etc. The Proximal Tibial Ring, Distal Tibial Ring and Foot Ring are designed with slots. This slot feature allows the fixation elements to slide to the desired position as opposed to the user having to handle small components (wire bolt and nut) to attach to the rings or taking the bolt out and placing it into a different hole. The system also includes tab rings with fixation holes to be used based on surgeon preference. As cleared in 510(k) K162033, the SALVATION External Fixation System is designed so that the SIDEKICK Circular and SIDEKICK EZ FRAME™ components are compatible and can be used with the SALVATION External Fixation system.

(a)(5). INTENDED USE

Wright's SALVATION™ External Fixation System is intended for:

- Fusions of the foot including:
  - Triple arthrodesis
  - Isolated hindfoot arthrodesis
  - Midfoot arthrodesis
  - Joints involved include tibiotalar, subtalar, talonavicular, calcaneocuboid, pantalar, tibio-talocalcaneus, naviculocuneiform, metatarsal cuneiform (first, second, third – e.g. Lapidus, TMT), metatarsal cuboid
- Treatment of fractures including:
  - Treatment of LisFranc fracture/dislocations in diabetic and Charcot neuropathy patient
  - Fractures and/or comminuted fractures (open or closed) of the calcaneus, talus, cuboid, navicular, cuneiforms, and/or metatarsals (including Jones fractures), ankle, and distal tibia
  - Additional fixation adjunct to internal fixation of the distal tibia, calcaneus, talus, navicular, cuboid, cuneiforms, and/or metatarsals in patients with significant comorbidities (i.e. diabetes) that may preclude use of isolated internal fixation
- Reconstruction of deformities including:
  - Neuropathic deformities
  - Charcot reconstruction with or without corrective osteotomies
  - Diabetic Charcot Reconstruction
  - Prevention and treatment of contracture of joints and tendons in equinus
- Treatment of infected unions, nonunions, or malunions
- Offloading and or immobilization of ulcers and/or wounds of the foot or ankle
- Stabilization associated with tendon or ligament surgeries. Tendon lengthening, repairs and transfers both deep and or superficial around the foot and ankle including posterior tibial, tibialis anterior, flexor digitorum longus, achilles, flexor hallucis longus, peroneus brevis, peroneus longus, extensor hallucis longus, extensor digitorum longus
- Tumor and neoplasm resection and reconstruction
- Stabilization associated with rotation flaps, free flaps, muscle flaps, advancement flaps, fasciocutaneous flap, split thickness skin grafting, biological graft alternatives
- Pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction osteogenesis including bone transport
- Correction of bony or soft tissue deformities
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- Use on long bones including the tibia and fibula
- Use with or without IM nail in the ankle in Charcot patients

(a)(6). Technological Characteristics Comparison

The subject devices included in the SALVATION™ External Fixation System Line Extension are technologically substantially equivalent to predicate devices in material, design features, size, and mechanical strength. The fundamental scientific technology of the modified device has not change relative to the predicate devices.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Mechanical Pull-out testing, Finite Element Analysis, and Engineering analysis demonstrated substantial equivalence comparing each modified component to the predicate components. The indications for use of the subject SALVATION™ External Fixation System are identical to the predicate SALVATION™ External Fixation System K162033.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate devices.