



Food and Drug Administration
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Wright Medical Technology, Incorporated
Ms. Leslie Fitch
Manager, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

January 13, 2016

Re: K153635

Trade/Device Name: SALVATION(R) 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: December 18, 2015

Received: December 18, 2015

Dear Ms. Fitch:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K153635

Device Name

SALVATION® External Fixation System

Indications for Use (Describe)

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-talo-calcaneus, naviculocuneiform, metatarsal cuneiform (1st, second, third – e.g. Lapidus, TMT), metatarsal cuboid
- Treatment of fractures including:
 - o Treatment of Lis Franc 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

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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:** December 18, 2015
- Contact Person:** Leslie Fitch
Manager, Regulatory Affairs
Office: (901) 867-4120
Fax: (901) 867-4190
- (a)(2). Proprietary Name:** SALVATION[®] External Fixation 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 Devices:** K150004: SALVATION[®] External Fixation System
K130044: SIDEKICK[®] EZ FRAME Fixator System
K100137: SIDEKICK[®] Circular Fixation System
K052005: R&R External Fixation System
- (a)(4). Device Description**

The SALVATION[®] External Fixation System consists of rings, wires, wire fixation bolts, wire posts with bolt, half pins, half pin cubes with bolts, bushings, rocker

plates, outsoles, insoles, etc. The Proximal and Distal Tibial Rings and Foot Ring are designed with slots.

The SALVATION® External Fixation System features 4 preassembled frame options: 160 MM FRAME with 160 mm proximal tibial ring, 140 mm distal tibial ring, and 140 mm foot ring; 180MM FRAME with 180 mm proximal tibial ring, 160 mm distal tibial and 160 foot ring; 200 MM FRAME with 200 mm proximal tibial ring, 180 mm distal tibial and 180 mm foot rings; and 220 MM FRAME (subject device) with 220 mm proximal tibial ring, 200 mm distal tibial and 200 mm foot ring. As cleared in 510(k) K150004, 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

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-talo-calcaneus, naviculocuneiform, metatarsal cuneiform (1st, second, third – e.g. Lapidus, TMT), metatarsal cuboid
- Treatment of fractures including:
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 - 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
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- 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

(a)(6). Technological Characteristics Comparison

The SALVATION® External Fixation System is technologically substantially equivalent to predicate devices in material, design features, and mechanical strength. The fundamental scientific technology of the modified device has not changed relative to the predicate devices.

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

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 the same as the indications cleared for the predicate SALVATION® EXTERNAL FIXATION K150004.

(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 device.