DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 24, 2017

Sonoma Orthopedic Products, Inc.
% Dawn Norman
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue
Suite 500
Memphis, Tennessee 38119

Re: K161371
Trade/Device Name: Sonoma Fifth Metatarsal Repair System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 26, 2017
Received: January 27, 2017

Dear Ms. Norman:

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.

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" (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.

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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161371

Device Name
Sonoma Fifth Metatarsal Repair System

Indications for Use *(Describe)*
The Sonoma Fifth Metatarsal Repair System is intended for use in the fixation of fractures and osteotomies of the fifth metatarsal, including Jones, avulsion and shaft 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K161371

510(k) Summary

Sonoma Fifth Metatarsal Repair System

February 24, 2017

Company: Sonoma Orthopedics Products, Inc.
1388 Busch Parkway
Buffalo Grove, IL 60089
Phone: 707-526-1335
Fax: 707-526-2022

Establishment Registration: 3007038372

Primary Contact: Dawn Norman, MS
Exec. Vice President
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, TN, 38119, USA
Phone: 618-604-3064
Fax: 707-526-2022

Company/Secondary Contact: Kyle Lappin
Sonoma Orthopedics Products, Inc.
1388 Busch Parkway
Buffalo Grove, IL 60089
Phone: 707-526-1335
Fax: 707-526-2022

Trade Name: Sonoma Fifth Metatarsal Repair System

Common Name: Rod, Fixation, Intramedullary and Accessories

Classification: Class II

Classification Name: Intramedullary fixation rod

Regulation Number: 888.3020

Panel: 87 - Orthopedic

Product Code: HSB

Predicate Device: K032548 IP-XS Compression Nail

Device Description: The Sonoma Fifth Metatarsal Repair System is intended for use in the fixation of fractures and osteotomies of the fifth metatarsal, including Jones, avulsion, and shaft fractures. The Fifth Metatarsal Repair System includes the Sonoma Fifth Metatarsal Nail, End Caps and related instruments. Sonoma's Fifth Metatarsal Nail differs from traditional nails or rods as it utilizes Sonoma's ActivLoc® fixation gripper system at the distal end of the rod to supplement distal fixation without the use of screws, threads or K-wires. The implants are composed of 316 stainless steel per ASTM F138.

Indications for Use: The Sonoma Fifth Metatarsal Repair System is intended for use in the fixation of fractures and osteotomies of the fifth metatarsal, including Jones, avulsion and shaft fractures.

Substantial Equivalence: The intended use of the subject device is substantially equivalent to the predicate device. The indications for use for the subject device are limited to the fifth metatarsal as opposed to additional anatomic locations indicated for the predicate device. The material of the subject device is the same as the IP-XS Nails (K032548). The dimensions of the subject device are within the range of the predicate device. The subject device utilizes a compressive end cap similar to the predicate IP-XS nail. Thus, the subject device is substantially equivalent to the predicate device.

Performance Testing: Engineering analysis and mechanical testing in a clinically relevant fracture model confirmed that the subject rods are equivalent to the predicate device in cyclic and static fatigue testing. Additional testing was performed demonstrating adequate fixation both during insertion and over time. The Sonoma Fifth Metatarsal Repair System meets the pyrogen limit specifications.