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## 510(k) Summary

SEP 28 2010

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| Submitter's name | Sonoma Orthopedic Products, Inc.<br>Santa Rosa, CA 95403 |
| Phone Number<br>Fax Number | 707-526-1335 ext 255<br>707-540-6001 |
| Name of contact person | Carlos Gonzalez |
| Date summary was prepared | September 28, 2010 |
| Proprietary name/Trade name | Sonoma CWG Clavicle Fracture Repair Device |
| Common Name | Intramedullary Fixation Device |
| Classification Name | 888.3020 Intramedullary fixation rod. |
| Predicate Devices | Sonoma Orthopedics CMx Clavicle Pin (K081832)<br>DePuy Rockwood Clavicle Pin (K991649) |
| Description of device | Sonoma CWG devices are 316L SS intramedullary fixation devices that utilize internal grippers for fixation, similar to the Sonoma CMx predicate and also use a compression screw similar to the predicate Rockwood pin, to compress the fracture. The device is available in 4 & 5mm OD and sizes 90-120mm in length. |
| Intended use of device | The Sonoma CWG Clavicle Fracture Repair device is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle. |
| Comparison to Predicate Devices | The Sonoma CWG Fracture repair device utilizes the same materials and similar construction as the predicate Sonoma CMx Clavicle pin (2 grippers, a wavy body and a straight section to carry the biomechanical load). The CWG does not include a cross-screw (as the predicate CMx) but rather includes a compression screw, similar to the DePuy Rockwood pin to compress the fracture fragments together. |
| Performance Data (Non clinical) | The "working" components of the Sonoma CWG are equivalent to the Sonoma predicate CMx when evaluated against ASTM F1264-03, see the list below. Clinical evaluation of the device is not required. |

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## *510(k) Summary of Non-clinical Performance Data Specifically Conducted for Sonoma CRx CWG*

**Tests to ASTM F1264-008**

An analysis of the Sonoma CRx CWG design versus the Sonoma CRx WG was conducted for static bending, torque, and cyclic bending fatigue test. The results are described in test report DVR 003-0035. This analysis demonstrates the subject device Sonoma CRx CWG is equivalent to the predicate device Sonoma CRx WG.

**In-Vitro Cyclic Fatigue Test**

Sonoma Orthopedic Products, Inc created a proprietary test that simulates representative biomechanical loading. These data demonstrated the subject design, Sonoma CRx CWG, is equivalent to the predicate device, Sonoma CRx WG. Data are included in TR 003-0031.

**Indications for Use Test**

Comparative, bilateral fixation and anatomical alignment tests were performed in cadaveric torso specimens with the Sonoma CRx WG in one clavicle and the Sonoma CRx CWG in the opposite clavicle. These data demonstrated substantial equivalence to the predicated device, Sonoma CRx WG, for fracture fixation and anatomical alignment through pendant range of motion of the affected appendage. Data are included in DVR 003-0042.

**Fixation Verification Test**

The cadaveric clavicle bone samples as implanted in the Indications for Use Tests (above) were explanted and the opposing tensile force to distract the fracture greater than 2 millimeters was measured. These data demonstrated the subject design, Sonoma CRx CWG, is equivalent to the predicate device, Sonoma CRx WG. Data are included in TR 003-0037.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Sonoma Orthopedic Products, Inc.
% Mr. Carlos Gonzalez
650 Larkfield Center, Suite C
Santa Rosa, CA 95403

SEP 28 2010

Re: K100112
Trade/Device Name: Sonoma CWG Clavicle Fracture Repair Device
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 17, 2010
Received: September 20, 2010

Dear Mr. Gonzalez:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K100112

Device Name: Sonoma CWG Clavicle Fracture Repair Device

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**INDICATIONS FOR USE**

The Sonoma CWG Clavicle fracture repair device is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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