510(k) Summary

K111550

Submitter's name Address	Sonoma Orthopedic Products, Inc. 3589 Westwind Blvd. Santa Rosa, CA 95403
Phone Number Fax Number Name of contact person Date summary was prepared	707-526-1335 707-526-2022 Charles L. Nelson June 30, 2011
Proprietary name/Trade name	Sonoma FasTrac Clavicle Fracture Repair Device
Common Name	Clavicle Pin
Classification Name	888.3020 Intramedullary fixation rod.
Predicate Device	Sonoma Orthopedic Products, Inc. K081832, EnsplintCMX, Depuy Rockwood Pin K991649
Description of device	The Sonoma FasTrac Clavicle Fracture Repair Devices are stainless steel or titanium intramedullary fixation devices that utilize threads for fixation and a hub with cross screw. The device is available in nominal 3, 4, 5, and 6mm nominal OD and sizes 70-150mm nominal lengths.
Intended use of device	The Sonoma FasTrac 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 Device	The Sonoma FasTrac Clavicle Fracture Repair Device is intended to be made of Ti-6Al-4V Titanium or 316L Stainless Steel. The Sonoma Orthopedic Products, Inc. K081832, CMX and Depuy Rockwood Pin K991649 are also made of stainless steel. The Sonoma FasTrac device achieved equivalent strength and fatigue performance to the predicate devices. The FasTrac device is secured in place with threads on one end and a cross screw or compression screw on the opposite end. The Sonoma FasTrac meets the mechanical requirements of ASTM F1264-03.
Performance Data (Non clinical)	The Sonoma FasTrac Clavicle Fracture Repair Device is equivalent to the predicate devices, the Sonoma Orthopedic Products, Inc. K081832, CMX and Depuy Rockwood Pin K991649. This determination was made from empirical testing and engineering analysis. Attached is the summary table of Performance Testing. Clinical evaluation of the device is not required.

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Performance Testing Summary

Test	Applicable Standard	Protocol/Report Number (Sonoma Fastrac)	Protocol/Report Number (Rockwood Pin and/or Ensplint CMx)	Conclusion	Equivalent
Dynamic Compression, Bending and Torsion	N/A	DVP-003-0046 DVR-003-0046	DVP/DVR-003-0013	The Sonoma FasTrac is substantially equivalent to the Ensplint CMx under compressive, bending and torsional loads in a simulated in-vivo environment with respect to the biomechanical loads.	Equivalent
Cyclic Bending Fatigue	ASTM F1264-03(07)	DVP-003-0044 DVR-003-0044	DVP/DVR-003-0002 DVP/DVR-003-0021	The bending fatigue properties of the predicate Depuy Rockwood Pin and the Sonoma FasTrac are substantially equivalent when tested under similar loading.	Equivalent
Static Bending	ASTM F1264-03(07)	DVP-003-0044 DVR-003-0044	DVP/DVR-003-0001 DVP/DVR-003-0022 TR-003-0009 TR-003-0018	The bending properties of the predicate Depuy Rockwood Pin and the Sonoma FasTrac are substantially equivalent when tested under similar loading.	Equivalent

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Static Torsion	ASTM F1264-03(07)	DVP-003-0044 DVR-003-0044	DVR-003-0008	The static torsional stiffness properties of the predicate device and the Sonoma FasTrac are substantially equivalent when tested under similar loading.	Equivalent
Indications for Use	N/A	None	DVP/DVR-003-0010	The Sonoma Fastrac is equivalent in size, configuration and fixation methods to the predicate devices and therefore demonstrates equivalent fixation and alignment properties.	Equivalent

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Sonoma Orthopedic Products, Inc.
% Mr. Charles L. Nelson
Chief Operating Officer
3589 Westwind Boulevard
Santa Rosa, California 95403

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Re: K111550
Trade/Device Name: Sonoma FasTrac Clavicle Fracture Repair Device
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: June 28, 2011
Received: June 29, 2011

Dear Mr. Nelson:

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): _K111550_____

Device Name: Sonoma FasTrac Clavicle Fracture Repair Device

INDICATIONS FOR USE

The Sonoma FasTrac 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mellerson

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

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Date 6/28/2011