OCT 1 0 2008

510(k) Summary

Submitter's name Address	Sonoma Orthopedic Products, Inc. 650 Larkfield Center, Suite C Santa Rosa, CA 95403
Phone Number Fax Number	707-526-1335 707-526-2022
Name of contact person	Charles L. Nelson
Date summary was prepared	June 30, 2008
Proprietary name/Trade name	EnsplintCM$_X$™ GWG (gripper-wavy-gripper) EnsplintCM$_X$™ GGW (gripper-gripper-wavy)
Common Name	Clavicle Pin
Classification Name	Intramedullary rod, 21 CFR 888.3020 Pin, Fixation, Threaded 21 CFR 888.3040
Predicate Device	DePuy Rockwood™ Clavicle Pin K991649, cleared July 14, 1999
Description of device	The Ensplint*CM*$_X$™ configuration consists of an implant made of 316 stainless steel.
Intended use of device	The Ensplint*CM*$_X$™ is intended to be used to repair an acute fracture, mal-union, or non-union of the clavicle
Comparison to Predicate Device	The Ensplint*CM*$_X$™ has similar intended use, performance characteristics, and materials to the predicate device.
Performance Data (Non clinical)	The results of the non-clinical (bench top and cadaver) laboratory testing demonstrate that the device is substantially equivalent. Clinical evaluation of the device is not required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2008

Sonoma Orthopedic Products, Inc.
% Mr. Charles L. Nelson
650 Larkfield Center, Suite C
Santa Rosa, CA 95403

Re: K081832
Trade/Device Name: EnsplintCM$_x$™ Clavicle Pin GWG (gripper-wavy-gripper)
EnsplintCM$_x$™ Clavicle Pin GGW (gripper-gripper-wavy)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 22, 2008
Received: September 22, 2008

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.

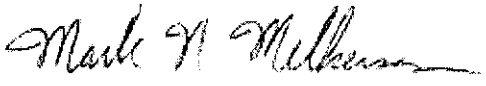
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081832

Device Name: ENSPLINTCMx™ Clavicle Pin GWG (gripper-wavy-gripper)
ENSPLINTCMx™ Clavicle Pin GGW (gripper-gripper-wavy)

Indications for Use:

INDICATIONS
The ENSPLINTCM$_X$™ Clavicle Pin 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K081832