510(K) SUMMARY

JUL 10 2008

Submitter's name:	Sonoma Orthopedic Products, Inc.
Address:	650 Larkfield Center, Suite C Santa Rosa, CA 95403
Phone Number:	707-526-1335 x-224
Fax Number:	707-526-2022
Contact Person:	Amy Conuel Director Quality Assurance & Regulatory Affairs
Date Prepared:	July 8, 2008
Trade Name:	Ensplint™ Bone Screw
Common Name:	Bone Screw
Classification Name:	Smooth or threaded metallic bone fixation fastener
Predicate Device:	Syntec-Taichung Non-Sterile Bone Plate and Screw Implants. K983495, cleared 12/16/1998
Device Description:	HA Cortical Self-Tapping Bone Screws in diameters of 1.5mm to 5.0mm and lengths of 4mm to 90mm.
Intended Use:	The Ensplint™ Bone Screws are intended to treat fractures of various small and long bones. The Ensplint™ Bone Screws can also be used with the EnsplintRx Distal Radius System.
Rationale for Substantial Equivalence / Comparison to Predicate:	The Ensplint™ Bone Screw utilizes the same material and technology characteristics as the Syntec Scientific Corp. Bone Screws and conforms to the ASTM F543-2 Standard Specification for HA Bone Screws. The diameters and lengths are within the diameters and lengths of the predicate Syntec Scientific Corp bone screws. Therefore testing is not needed to demonstrate that the subject devices are substantially equivalent to other legally marketed bone screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sonoma Orthopedic Products, LLC
% Ms. Amy Conuel
Director, Quality Assurance/Regulatory Affairs
650 Larkfield Center, Suite C
Santa Rosa, California 95403

JUL 10 2008

Re: K080778
Trade/Device Name: Ensplint™ Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulation Class: Class II
Product Code: HWC
Dated: June 24, 2008
Received: June 25, 2008

Dear Ms. Conuel:

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.

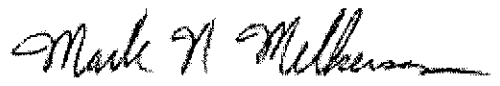
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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): K080778

Device Name: Ensplint™ Bone Screw

Indications for Use:

The Ensplint™ Bone Screws are intended to treat fractures of various small and long bones. The Ensplint™ Bone Screws can also be used with the EnsplintRx Distal Radius System.

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)

Barbara Bucher D for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080778