K111608(1/2)

AUG 29 2011

5. 510(k) Summary

Device Trade Name:	SLIC Screw Repair System
Manufacturer:	Acumed, LLC 5885 NW Cornelius Pass Road Hillsboro, OR 97124
Contact:	Ms. Lino Tsai Regulatory Specialist Phone: 503.627.9957
Prepared by:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	June 8, 2011
Classification:	21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener
Class:	II
Product Code:	HWC

Indications For Use:
The SLIC Screw Repair System is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

Device Description:
The SLIC Screw Repair System consists of a headless, cannulated two-piece screw assembly. The two-piece design incorporates the use of distal and proximal screw components to anatomically reduce two bones.

The purpose of this Special 510(k) is to modify the material, interconnection geometry and available sizes of the SLIC Screw. All components are made of 22-13-5 stainless steel conforming to ASTM F1314. These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Predicate Device:
The modified SLIC Screw Repair System is substantially equivalent to the predicate ARC Surgical Bone Reduction System (K063244) with respect to indications, design, function, and materials.

Preclinical Testing:
The new components were subjected to insertion testing, pull-apart testing and pull-out strength testing. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.

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

Acumed, LLC
% Ms Lino Tsai
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

AUG 29 2011

Re: K111608
Trade/Device Name: SLIC Screw Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bond fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 5, 2011
Received: August 8, 2011

Dear Ms. Tsai:

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

K111608 (1/1)

4. Indications for Use

510(k) Number (if known): _____

Device Name: SLIC Screw Repair System

The SLIC Screw Repair System is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

Prescription Use ___√___ (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)

for M Mellerson

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

510(k) Number K111608