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K093078

Bonutti Research, Inc.
Unity Ultrasonic System with PLLA Fasteners
June 3, 2010

JUN 23 2010

510(k) SUMMARY

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367
Effingham, Illinois 62401
Phone: (217) 342-3412, ext. 321
Fax: (217) 342-1043

Date Prepared: June 3, 2010

Proprietary Name: Unity Ultrasonic System with PLLA Fasteners

Common Name: Fixation Device

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue.

Device Description: The Unity Ultrasonic System with PLLA Fasteners is designed for the fixation of soft tissue, ligament, tendon, and bone. Absorbable poly-L-lactic acid (PLLA) implant materials are ultrasonically welded, staked, and/or joined to secure soft tissue, ligament, tendon, and bone at a repair site. An electrical generator provides ultrasonic energy to the end effector of a handpiece to fix the implant materials together and secure soft tissue, ligament, tendon, and/or bone. Energy applied to the trailing end of the implant portion contacting the handpiece end effector joins this implant portion to the other implant portion in securing soft tissue, ligament, tendon, and bone. Ultrasonic handpieces with end effectors designed to accommodate Unity Implants are product specific and include a force sensor mechanism that allows the surgeon feedback on the amount of load they are applying to the handpiece. Feedback is provided to the surgeon through an audible tone.

Indications for Use: The Unity Ultrasonic System with PLLA Fasteners consists of an electrical generator and ultrasonic handpieces. The system is to be used with Unity single patient use absorbable (PLLA) implants intended for use as fasteners (anchors) in the fixation of tissue, ligament, tendon, and bone. The system is indicated in general soft tissue approximation/ligation.

K093078

Predicate Device(s): The Unity Ultrasonic System with PLLA Fasteners is similar in design and intended use to existing Bonutti Research, Inc., ultrasonic systems (electrical generators and ultrasonic handpieces) and Unity Implants used in sutureless fixation and previously determined substantially equivalent.

Predicate Comparison: The modification to the Unity Ultrasonic System with PLLA Fasteners to its predicate ultrasonic systems includes the addition of a 40 kHz handpiece to the existing 20 kHz handpiece. Both handpieces are used with the same electrical generator to ultrasonically weld, stake, and/or join absorbable poly-L-lactic acid (PLLA) implant portions together to secure soft tissue, ligament, tendon, and bone at a repair site. The 40 kHz handpiece is similar in design, packaging, and labeling to its predicate handpiece. Each handpiece has similar cleaning and sterilization techniques.

Predicate Verification: Design verification testing with identified acceptance criteria conducted to determine substantial equivalence among the predicate devices noted in the preceding section included; (1) A comparison of the mechanical strengths and failure modes among the two handpieces and their respective implants when ultrasonically welded. Implant strengths were statistically equivalent among the respective implants tested. (2) An electrical safety and EMC test plan with related acceptance criteria was defined. (3) A risk evaluation of the 40 kHz handpiece to its predicate demonstrated similar design, packaging, labeling, and sterilization techniques that raise no concerns regarding the safe and effective use of the Unity Ultrasonic System with PLLA Fasteners.

Submitted by:

Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA

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

JUN 23 2010

Bonutti Research, Inc
% Mr. Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
P.O. Box 1367
Effingham, Illinois

Re: K093078
Trade/Device Name: Unity Ultrasonic System with PLLA Fasteners
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: June 3, 2010
Received: June 4, 2010

Dear Mr. Balsmann:

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: K093078

Device Name: Unity Ultrasonic System with PLLA Fasteners

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Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

Jonette D for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093078