

12092594

SEP 16 2009

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name: ACE Surgical Supply Co., Inc.
Submitter Address: 1034 Pearl St., Brockton, MA 02301
Contact Person: J. Edward Carchidi, DDS
Phone Number: (508) 588-3100
Fax Number: (508) 523-3140
Date Prepared: August, 2009
Device Trade Name: ACE Surgical Secure-Mini™ Locator® Implant System
Device Common Name: Endosseous Implant Screw
Classification Name: Implant, Endosseous, Root form, product code DZE
Predicate device: ACE Surgical Secure-Mini™ Implant System, K073343
Zest Locator Implant Anchor, K994257
Zest Modification to Locator Implant Anchor, K072878
Reason for submission: Not previously marketed in the USA

Device Description and Materials:

The ACE Secure-Mini™ Locator® Implant System is an additional set of machined surgical grade titanium alloy (Ti-6Al-4V ELI) screw implants to the Secure-Mini™ product family, intended to provide immediate transitional splinting stability or intra-bony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients. The implants are supplied sterile in 2.3 mm diameter, and in lengths of 10, 11.5, 13, and 15 mm, and with Zest Locator® Implant Anchor Abutments (cleared under K994257) and Denture Cap Males (cleared under K072878) in standard tray packaging and include placement instruments.

The screw raw material is Ti-6-AL-4V ELI per ASTM F136 standard. The candidate devices are identical in materials and characteristics to that cleared under K073343. These screws are supplied sterile in standard Tyvek™ trays.

The ACE Surgical Secure-Mini™ Locator® Implant System is a comprehensive system retaining prosthetic components, auxiliary components, and surgical tools as does the predicate ACE Surgical Secure-Mini™ Implant system.

Intended Use:

The ACE Surgical Secure-Mini™ Implant System is intended to provide immediate transitional splinting stability or intra-bony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients.

Substantial Equivalence/ Device - Technological Characteristics and Comparison to Predicate Device(s):

The ACE Surgical Secure-Mini™ Locator® Implant System is substantially equivalent to the ACE Surgical Secure-Mini™ Implant System, K073343, Zest Locator Implant Anchor, K994257, and Zest Modification to Locator Implant Anchor, K072878.

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE Surgical Secure-Mini™ Locator® Implant System to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the ACE Surgical Secure-Mini™ Locator® Implant System and the specified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 16 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

J. Edward Carchidi, DDS
President
ACE Surgical Supply Company, Incorporated
1034 Pearl Street
Brockton, Massachusetts 02301

Re: K092594
Trade/Device Name: ACE Surgical Secure-Mini™ Locator® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 17, 2009
Received: August 24, 2009

Dear Dr. Carchidi:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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,



Susan Runner, D.D.S., M.A.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: 12092594

Device Name: ACE Surgical Secure-Mini™ Locator® Implant System

Indications For Use:

The ACE Surgical Secure-Mini™ Locator® Implant System is designed to provide immediate transitional splinting stability or intra-bony long term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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