K093518

ATTACHMENT 1



# 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.

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| 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: | November, 2009 |
| Device Trade Name: | ACE Surgical Secure™ Locator® 3.25mm Implant System |
| Device Common Name: | Endosseous Implant Screw |
| Classification Name: | Implant, Endosseous, Root form, product code DZE, Endosseous Dental Implant Abutment, product code NHA |
| Predicate device: | ACE Surgical Secure-Mini™ Locator® Implant System, K092594 ACE Screw Dental Implant System, K954513 |
| Reason for submission: | Not previously marketed in the USA |

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**Device Description and Materials:**

The ACE Secure™ Locator® 3.25mm Implant System is a set of machined commercially pure (CP) titanium (Grade 4) screws, intended to provide intra-bony long term fixation of denture installations in partially or fully edentulous patients. The implants are supplied sterile in 3.25 mm diameter, and in lengths of 8, 10, 11.5, 13, and 15 mm, and with Zest Locator® Implant Anchor Abutments and Denture Cap Males (identical to those cleared under K092594)in standard tray packaging and include placement instruments.

The screw raw material is TI (CP-Grade 4) per ASTM F67 standard. The screw implants, abutments and denture caps are identical in materials and characteristics to that cleared under K092594 and K954513. These screws are supplied sterile in standard Tyvek™ tray packaging along with applicable instructions for use.

The ACE Secure™ Locator® 3.25mm Implant System is a comprehensive system using same and similar surgical tools (a Two Step Lag Bur CA is replaced by a Kirschner Pilot Bur, and the optional Parallel Pin/Depth Gauge and 2.8 mm twist drill are now supplied standard) made from high strength corrosive resistant stainless steel (17-4, H-900) and a similar (the predicate tray had holes and markings to accommodate the predicate screw implant sizes, the candidate device will have two trays – one solely for candidate screw implant sizes, and another for the combined predicate and candidate screw implant sizes) polycarbonate sterilization tray accessory as in the predicate ACE Surgical Secure-Mini™ Locator® implant system.

**Intended Use:**

ACE Surgical Secure™ Locator® 3.25mm Implant System is is designed to provide intra-bony long term fixation of denture installations in partially or fully edentulous patients.

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

The ACE Surgical Secure™ Locator® 3.25mm Implant System is substantially equivalent to the ACE Surgical Secure-Mini™ Locator® Implant System, K092594 and the ACE Screw Dental Implant System , K954513.

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE Surgical Secure™ Locator® 3.25mm Implant System to the specified predicate devices are: 1) device description, 2) indications for use and intended use(s), 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the fundamental technology, performance, safety, or effectiveness between the ACE Surgical Secure™ Locator® 3.25mm Implant System and the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

JAN 1 4 2010

Re: K093518
Trade/Device Name: ACE Surgical Secure™ Locator® 3.25mm Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 14, 2009
Received: December 16, 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,

for

Anthony D. Watson, BS, MS, MBA
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:*** K093518

***Device Name:*** ACE Surgical Secure™ Locator® 3.25mm Implant System

***Indications For Use:***

The ACE Surgical Secure™ Locator® 3.25mm Implant System is is designed to provide intra-bony long term fixation of 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B&Betz DDS for Dr. K.P. Mulroy (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices



510(k) Number: K093518