DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

J. Edward Carchidi, D.D.S.
President
Ace Surgical Supply Company, Incorporated
1034 Pearl Street
P.O. Box 1710
Brockton, Massachusetts 02403

Re: K981526
Trade Name: Ace Alveolar Distractor
Regulatory Class: II
Product Code: JEY
Dated: August 10, 1998
Received: August 11, 1998

Dear Dr. Carchidi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name:_____

Indications For Use:

Re: K981526

Indications for Use

Indications:

The ACE Surgical Alveolar Distraction Fixture is designed for use in totally or partially edentulous mandibles or maxillae to increase bone height and mass by means of distraction osteogenesis. As clinically defined the gradual step lengthening of a callus for distraction osteogenesis can be achieved with the transitory use of the ACE Surgical Alveolar Distractor. This ACE Surgical transitory monofocal distraction device is indicated for use in maxillofacial alveolar and small craniofacial skeletal bones.

Contraindications:

The ACE Surgical Alveolar Distraction Fixture is contraindicated in patients with insufficient available bone, poor bone quality, and generalized diseases, allergies or habits (uncontrolled diabetes, blood dycrasias, hyperthyroidism, AIDS, alcohol addiction, psychiatric disorders, oral infections, malignancies, myocardial infarction within the last 12 months, heavy smoking, use of chewing tobacco, poor oral hygiene, etc.) that may contribute to poor healing or osteogenesis formation of bone. The patient's good medical health status and history is mandatory. In addition, a radiographic evaluation to examine the anatomical condition of the patient for proper use of the device to the defined surgical protocol is required.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981526