ZEST ANCHORS, INC.

MAR 17 2000

K994257

Attachment 6

510 (k) Summary of Safety and Effectiveness Information

Preparation Date: December 15, 1999
Zest Anchors, Inc.
2061 Wineridge Place #100
Escondido, CA 92029

Phone # 760-743-7744
Fax # 760-743-7975
Contact Person: Paul Zuest, President

Trade Name: Locator Implant Anchor
Common Name: Abutment for Endosseous Implant
Classification Name: Endosseous Dental Implant (accessory) 76DZE

The legally marketed device to which our firm is claiming equivalence is identified as the ZAAG Implant Anchor manufactured by Zest Anchors, Inc., and cleared for market under K934668. The predicate device is an abutment for endosseous implants which is intended for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

The 510 (k) notification is based upon the fact that there are no significant differences between the Locator Implant Anchor (subject of this submittal) and the ZAAG Implant Anchor (predicate device) in terms of indications for use, design, and materials.

The most significant functional requirement of the devices is the value of the retentive force. Experience has shown that it should fall between 3.0 pounds and 5.0 pounds. Removal retention force was measured for both the Locator Implant Anchor and the ZAAG Implant Anchor. Mean values were 4.7 pounds (SD = .207) for the Locator Implant Anchor, and 4.2 pounds (SD = .483) for the ZAAG Implant Anchor.

Safety of the devices can be influenced by their ability to withstand occlusal forces in a divergently placed implant fixture. The Locator Implant Anchor and ZAAG Implant Anchor share the exact same Angle Correction Base which threads into a mal-aligned endosseous implant. Results of fatigue testing of the Angle Correction Base show that, under the most severe conditions (25 degree angled component with a 4mm gingival cuff height), after 5 million cycles of compression testing, the fatigue strength of the attachment components is still at least 175 pounds.

In conclusion, this 510 (k) Summary is based upon the facts drawn from the results of testing which indicate the determination of substantial equivalence between the Locator Implant Anchor (subject of this submittal) and the ZAAG Implant Anchor (predicate device).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Mr. Paul Zuest
President
Zest Anchors, Inc.
2061 Wineridge Place, Suite 100
Escondido, California 92029

Re: K994257
Trade Name: Locator Implant Anchor
Regulatory Class: III
Product Code: DZE
Dated: December 15, 1999
Received: December 17, 1999

Dear Mr. Zuest:

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) 594-4690. 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

K994257

510(k) Number (if known): K99-4257

Device Name: Locator Implant Anchor

Indications For Use: The Locator Implant Anchor abutment for endosseous dental implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K994257

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

(Optional Format 1-2-96)