510(k) Summary
Zest Anchors, LLC
Chairside® Attachment Processing Material
K140570

June 3, 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name	Zest Anchors, LLC 2061 Wineridge Place Escondido, CA 92029 Telephone: +1 (760) 743-7744 ext. 140 Fax: +1 (760) 743-7975
Official Contact	Annie Wright Regulatory Affairs Manager
Representative/Consultant	Kevin A. Thomas, Ph.D. Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Chairside® Attachment Processing Material
Common Name	Resin, denture, relining, repairing, rebasing
Classification Name	Denture relining, repairing, or rebasing resin
Classification Regulations	Class II, 21 CFR 872.3760
Product Code	EBI
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Chairside® Attachment Processing Material is a dual cure (either self or UV light) pink composite used to process attachments into dentures in a chairside or laboratory procedure.

DEVICE DESCRIPTION

Chairside Attachment Processing Material is a composite that is used to secure denture cap attachments into dentures. These attachments are commonly used in conjunction with dental implants to assist in affixing dentures to the wearer. Chairside Attachment Processing Material can be used chairside (to pick up the attachments from the mouth of the patient) or in a laboratory setting (using a model of the patient's mouth).

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent to the following predicate devices:

- VOCO GmbH, Quick Up (K110440)
- IMTEC Corporation, SECURE (K021586)
- Danville Materials, Inc., Starfill 2B HV, Starfill 2B LV (K092912)
- DMG USA, Inc., Flowable Composite (K011211)

The subject device, Chairside Attachment Processing Material, has a similar formula to the device cleared in K092912. The subject device is both self-curing and UV-light curing similar to those cleared in K110440, K021586, and K092912. The application of the subject device is similar to those cleared in K110440, K021586, and K092912. The intended use of the subject device is similar to those cleared in K110440, K021586, and K011211.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included performance testing. Performance testing to demonstrate substantial equivalence included methods described in the standards ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers* and ISO 4049 *Dentistry – Polymer-based restorative materials.* The following testing was performed:

- Flexural strength per ISO 20795-1
- Flexural modulus per ISO 20795-1
- Water Sorption per ISO 4049
- Water Solubility per ISO 4049

Clinical data were not submitted in this premarket notification.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, Chairside Attachment Processing Material has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 16, 2014

Zest Anchors, LLC
c/o Kevin A. Thomas, PhD
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K140570
Trade/Device Name: Chairside® Attachment Processing Material
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: April 10, 2014
Received: April 11, 2014

Dear Dr. Thomas:

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 contact 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K140570

Device Name: Chairside® Attachment Processing Material

Chairside® Attachment Processing Material is a dual cure (either self or UV light) pink composite used to process attachments into dentures in a chairside or laboratory procedure.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Page 1 of 1

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