K140894

JUL 3 1 2014

*Alloy Makers To The World*

ARGEN

THE ARGEN CORPORATION
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San Diego, CA 92121-4718
United States of America
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# 510(k) Summary

**Submitted by:** The Argen Corporation
5855 Oberlin Drive, San Diego, CA 92121
(858) 455-7900 x471 (PHONE), (858) 626-8686 (FAX)

**Contact person:** Craig Jolicoeur

**Date prepared:** 4/02/2013

**Trade name:** ARGEN PMMA
**Common name:** PMMA Resin
**Classification name:** Temporary Crown and Bridge Material
(21 CFR 872.3770 Product Codes EBG, ELM)

**Legally marketed devices for which our organization is claiming substantial equivalence:**

| 510(k) Number | Trade Name | Manufacturer |
|---|---|---|
| K102341 | VIPI Block | VIPI INDUSTRIA, COMERCIO, EXPORTACAO E IMPORTACAO DE |
| K071548 | WIELAND ZENO CAO TEMPORARY PMMA DISC, TOOTH-COLORED | MERZ DENTAL GMBH |
| K061809 | EGRAL IMCROWN | MERZ DENTAL GMBH |
| K060293 | TEMPORARY CROWN AND BRIDGE MATERIAL | DENTSPLY INTERNATIONAL, INC. |

**Device Description:** Polymethylmethacrylate (PMMA) discs or blanks for use in dental CAD/CAM systems.

**Intended Use:** ARGEN PMMA Discs are polymethylmethacrylate blanks for dental use. These blanks are used to mill long-term temporary substructures for crowns & bridgework. The blanks are intended to be used in various CAD/CAM systems.

**Predicate devices:** K071548, K061809, K060293.

**Summary of the physical testing conducted on the device:**

ARGEN PMMA discs are substantially equivalent and/or identical to the dental devices listed above.
The proposed and predicate devices are both composed of polymethylmethacrylate. A hot cured polymer, and have similar indications for use. The proposed and predicate devices have similar physical and chemical properties. The polymerization grade of both devices is high. In addition, they have the same aesthetic function.

We can conclude that ARGEN PMMA discs have comparable technological characteristics to the predicate device.

**Summary of the biological testing conducted on the device:**

Although this device comes into direct contact with the patient, the material is considered to be non-toxic. The material was tested in accordance with ASTM F895-84:1984, ISO 10993.5:1999 and US Pharmacopeia XXVIII.
PMMA resin continues to be the universal versatile polymer in denture dentistry.
The Acrylic PMMA block has the same biological performance as substantially equivalent Dental Acrylic teeth.

**Substantial equivalence:**

The proposed and predicate devices are composed of a polymethyl metacrylate hot cured polymer. All devices have similar indications for use. The proposed and predicate devices have similar physical and chemical properties. All devices have comparable e-modulus, flexural strength and deflection. The polymerization grade of both devices is high. And they have the same aesthetic function.

Conclusion:
We are claiming substantial equivalence of the ARGEN PMMA disc to the predicate devices.

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

July 31, 2014

The Argen Corporation
Mr. Craig Jolicoeur
Quality & Regulatory Manager
5855 Oberlin Drive
San Diego, CA 92121-4718

Re: K140894
Trade/Device Name: ARGEN PMMA
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: May 2, 2014
Received: May 5, 2014

Dear Mr. Jolicoeur:

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 Industry and Consumer Education 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 Industry and Consumer Education 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.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use Statement

510(k) Number (if known): K140894

Device Name: ARGEN PMMA

Indications For Use:

ARGEN PMMA Discs are polymethylmethacrylate blanks for dental use. These blanks are used to mill long-term temporary substructures for crowns & bridgework. The blanks are intended to be used in various CAD/CAM systems.

Prescription Use _X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Sheena A. Green -S
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