



# Scientific Facts

Scientific Information and test results about Crystal Zirconia, including FDA registration materials, university studies and reports, and independent industry testing and results.



Department of Mechanical and Aerospace Engineering  
P. O. Box 876106  
Tempe, AZ 85287-6106

January 27, 2009

To Whom It May Concern:

Yttria stabilized Zirconia specimens were fabricated and tested in 3-point bending according to the ISO-6872 standard to evaluate the flexure strength of this product as required by the FDA.

Results from the 10 specimens required by the standard resulted in an average flexure strength of 1380 MPa with an average deviation of 60 MPa. These results indicate that the flexure strength of these samples is substantially greater than the minimum flexure strength of 50 MPa specified in the ISO standard.

Sincerely

A handwritten signature in black ink that reads 'Pedro D. Peralta'.

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Pedro D. Peralta, PhD  
Associate Professor  
Director, Mechanical Testing Laboratory  
Department of Mechanical & Aerospace Engineering  
Arizona State University



January 28, 2009

Rich McComas  
Dental Laboratory Milling Supplies

Subject: Chemical Solubility Test Report  
Job Number: S09N5841  
PO Number: CC

Dear Rich:

Please find enclosed the final report for the analysis of your sample.

Thank you for using the analytical services of the Evans Analytical Group - NY. We appreciate your business and welcome any suggestions you may have for improving the quality and efficiency of our service. Please do not hesitate to call us if you have any questions regarding this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Francisco Nam". The signature is written in a cursive style.

Kwan H. Francisco Nam, Ph.D.  
Program Manager  
(Tel. 315-431-9900; [knam@eaglabs.com](mailto:knam@eaglabs.com))

Enclosures:



**CHEMICAL SOLUBILITY TEST REPORT**

**JOB NUMBER: S09N5841**  
**PO NUMBER: CC**

for

Rich McComas  
Dental Laboratory Milling Supplies

Analyzed by:

A handwritten signature in black ink, appearing to read "Gabriel Infantino", written over a horizontal line.

Gabriel Infantino  
Lead Analyst  
(Tel. 315-431-9900; [ginfantino@eaglabs.com](mailto:ginfantino@eaglabs.com))

Reviewed by:

A handwritten signature in black ink, appearing to read "Francisco Nam", written over a horizontal line.

Kwan H. Francisco Nam, Ph.D.  
Program Manager  
(Tel. 315-431-9900; [knam@eaglabs.com](mailto:knam@eaglabs.com))

Evans Analytical Group  
6707 Brooklawn Parkway  
Syracuse, NY 13211, USA

Customer: **Dental Laboratory Milling Supplies**

P.O.#

CC

Date: 26-Jan-2009

Job #

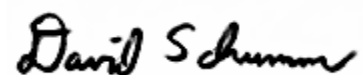
S09N5841

Customer ID: **ZrO2**  
**#2**

Shiva ID:

S090122047

Element	Concentration [ ppm wt ]	Element	Concentration [ ppm wt ]
Li	-	Ag	-
Be	-	Cd	-
B	-	In	Binder
O	Matrix	Sn	-
F	-	Sb	-
Na	-	Te	-
Mg	-	I	-
Al	-	Cs	-
Si	-	Ba	-
P	-	La	-
S	-	Ce	-
Cl	-	Pr	-
K	-	Nd	-
Ca	-	Sm	-
Sc	-	Eu	-
Ti	-	Gd	-
V	-	Tb	-
Cr	-	Dy	-
Mn	-	Ho	-
Fe	-	Er	-
Co	-	Tm	-
Ni	-	Yb	-
Cu	-	Lu	-
Zn	-	Hf	-
Ga	-	Ta	-
Ge	-	W	-
As	-	Re	-
Se	-	Os	-
Br	-	Ir	-
Rb	-	Pt	-
Sr	-	Au	-
Y	-	Hg	-
Zr	Matrix	Tl	-
Nb	-	Pb	-
Mo	-	Bi	-
Ru	-	Th	-
Rh	-	U	0.13
Pd	-		



**Purpose:**

To test for chemical solubility of zirconia pieces.

**Method:**

The chemical solubility test was performed in reference to *ANSI/ADA Specification No. 69-1999; Modified adoption of ISO 6872:1995, Dental ceramic.*

Experimental conditions:

Solubility contact time: 16 hours  
 Solubility test temperature: 80 °C  
 Contact solution: 4% (v/v) of acetic acid (VWR); DI water used = 18.2 MΩcm  
 Oven: Blue M ESP-400BC-4  
 Balance: Denver Instrument Company TL-204

**Table 1.** Solubility test contact conditions

Sample	total surface area all pieces, cm <sup>2</sup>	Contact solution volume, mL
ZrO <sub>2</sub> #1 (9 pieces)	26.5	88.33

**Results:**

Table 2 shows the results of the chemical solubility test. The pieces were pretreated and post treated according to the specification prior to weighing.

**Table 2.** Total solubility based on weight loss of zirconia blocks

Sample	Weight of pieces before contact g	Weight of pieces after contact g	Solubility µg/cm <sup>2</sup>
ZrO <sub>2</sub> #1 (9 pieces)	16.30048 *	16.30025 *	8.49

\* These values are the averages of four separate measurements



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dental Laboratory Milling Supplies  
Mr. Scott Atkin  
14201 North 87<sup>th</sup> Street  
Suite A-105  
Scottsdale, Arizona 85260

FEB 10 2009

Re: K082137  
Trade/Device Name: DLMS-Zirblocks  
Regulation Number: 872.6660  
Regulation Name: Porcelain Powder For Clinical Use  
Regulatory Class: II  
Product Code: EIH  
Dated: February 4, 2009  
Received: February 5, 2009

Dear Mr. Atkin:

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 such 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.

Page 2 – Mr. Atkin

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), 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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Ginette Y. Michaud, M.D.

Acting 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 (if known): K080237

Device Name: DLMS-Zirblocks

### Indications for Use:

Intended for use in CAD/CAM technology to produce copings, bridges, and framework core material usage for fixed prosthodontics. Then veneered with porcelain glass to create final restoration.


Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K080237