Scientific Facts

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

March 2009

ARIZONA STATE UNIVERSITY MAIN
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

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

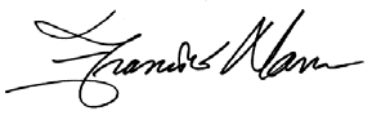
Subject: Chemical Solubility Test Report
Job Number: S09N5841
PO Number: CC

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,



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

Enclosures:

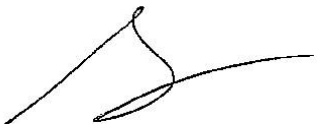
CHEMICAL SOLUBILITY TEST REPORT

JOB NUMBER: S09N5841
PO NUMBER: CC

for

Rich McComas
Dental Laboratory Milling Supplies

Analyzed by:



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

Reviewed by:

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

Evans Analytical Group
6707 Brooklawn Parkway
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GDMS
ANALYTICAL REPORT

SHIVA Technologies
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Syracuse, New York 13211

Telephone (315) 431-9900
Fax: (315) 431-9800
Email info.ny@eaglabs.com
www.eaglabs.com

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	-		

Accreditations: ISO/IEC 17025, Nadcap

Reviewed by David Schumm

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 ^{o}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^2	Contact solution volume, mL
ZrO_2 #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 $\mu g/cm^2$
ZrO_2 #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 87th 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.

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" (21CFR 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

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): K082137

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 ___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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sonya Purvis

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

510(k) Number: K082137