



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K081981 - 128 pages
COMPANY: LANG DENTAL MFG. CO., INC. (LANGDENT)
PRODUCT: RESIN, DENTURE, RELINING, REPAIRING, REBASING (EBI)
SUMMARY: Product: LANG DENTAL ACRYLIC PRIMER

DATE REQUESTED: Mar 22, 2016

DATE PRINTED: Apr 11, 2016

Note: Printed





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2008

Chah M. Shen, Ph.D
Director of Research and Development
Lang Dental Manufacturing Company, Incorporated
175 Messner Drive
P.O. Box 969
Wheeling, Illinois 60090-0969

Re: K081981
Trade/Device Name: Lang Dental Acrylic Primer
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: November 10, 2008
Received: November 12, 2008

Dear Dr. Shen:

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,



Chiu S. Lin, Ph. D *FOR DR. CHIU LIN*
Division 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):

Device Name: Lang Dental Acrylic Primer

Indications for Use:

LANG DENTAL Acrylic Primer is intended for use as an acrylic bonding agent when adding new acrylic to existing denture base acrylic.

Prescription Use X
(21 CFR part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR part 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081981

Page 1 of _____



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2008

Chah M. Shen, Ph.D
Director of Research and Development
Lang Dental Manufacturing Company, Incorporated
175 Messner Drive
P.O. Box 969
Wheeling, Illinois 60090-0969

Re: K081981
Trade/Device Name: Lang Dental Acrylic Primer
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
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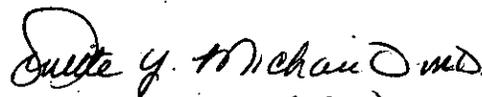
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Sincerely yours,



Chiu S. Lin, Ph. D *FOR DR. CHIU LIN*
Division 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):

Device Name: Lang Dental Acrylic Primer

Indications for Use:

LANG DENTAL Acrylic Primer is intended for use as an acrylic bonding agent when adding new acrylic to existing denture base acrylic.

Prescription Use X
(21 CFR part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR part 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: KCF 1987

Page 1 of _____

September 24, 2008

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

LANG DENTAL MFG. CO., INC.
175 MESSNER DR.
WHEELING, IL 60090
ATTN: CHAH M. SHEN

510(k) Number: K081981
Product: LANG DENTAL
ACRYLIC PRIMER

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(1)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 11, 2008

LANG DENTAL MFG. CO., INC.
175 MESSNER DR.
WHEELING, IL 60090
ATTN: CHAH M. SHEN

510(k) Number: K081981
Received: 11-JUL-2008
Product: LANG DENTAL ACRYLIC
PRIMER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K081981

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) LANG DENTAL MANUFACTURING CO INC 175 MESSNER DRIVE Wheeling IL 60090 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 362374355	2. CONTACT NAME Chah Shen 2.1 E-MAIL ADDRESS chahshen@hotmail.com 2.2 TELEPHONE NUMBER (include Area code) 847-2156622-223 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 847-2156678	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)		
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: (b)(4)		
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		07-Jul-2008

Form FDA 3401 (01/2007)

"Close Window" Print Cover sheet

Chah Shen

K9
DE
II

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 07/08/2008	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
----------------------------------	--------------------------------------	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Lang Dental Manufacturing Co., Inc.		Establishment Registration Number (if known) 1417322	
Division Name (if applicable)		Phone Number (including area code) (847) 215-6622	
Street Address 175 Messner Drive		FAX Number (including area code) (847) 215-6678	
City Wheeling	State / Province IL	ZIP/Postal Code 60090	Country USA
Contact Name Chah M. Shen			
Contact Title Director of Research and Development		Contact E-mail Address cshen@langental.com or chahshen@hotmail.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2

REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (specify):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (specify): Polymethyl methacrylate resin containing diethyl phthalate and free of benzoyl peroxide will be used instead of acrylic lacquer for the manufacturing of Lang Dental Acrylic Primer. Acetone will also be used to facilitate the dissolution of the resin to form a clear solution.		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KLE	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	NA/ A pre-amendment device	1 Lang Dental Acrylic Primer	1 Lang Dental Manufacturing Co., Inc.
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Acrylic Primer
Resin Tooth Bonding Agent

	Trade or Proprietary or Model Name for This Device	Model Number
1	Acrylic Primer 1-oz Bottle (30 ml)	1 REF 1602
2		2
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code KLE	C.F.R. Section (if applicable) 21CFR872.3200	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Dental Product		

Indications (from labeling)

Lang Dental Acrylic Primer is intended for use as an acrylic bonding agent.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

June 23, 2008

To: Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Attention: Document Control Clerk

RE: 510(k) Notification

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, this pre-market notification is being submitted at least 90 days prior to the proposed introduction into Interstate Commerce for the following device:

Classification Name: Dental Product

Proprietary Name: Lang Dental Acrylic Primer

Common/Usual Name: Acrylic Primer

Establishment Registration Number: 1417322

Classification: Class II

Classification Name: Resin Tooth Bonding Agent

Product Code: KLE

In order to comply with the SMDA of 1990, please be advised that the safety and effectiveness information will be made available to interested persons upon request.

Substantial Equivalence: This product is substantially equivalent to the original Lang Dental Acrylic Primer manufactured by Lang Dental Manufacturing Co., Inc., a pre-amendment device.

We understand that the submission of false information to the government is strictly prohibited by 18 U.S.C. 1001 and 21 U.S.C.331 (q).

If you have any questions or require additional information or date please call me at (847) 215-6622.

Received
JUL 11 2008
FDA CDRH DMC

Page 2 of 2

Sincerely,

A handwritten signature in black ink, appearing to read "Chah M. Shen". The signature is written in a cursive style with a large initial "C".

Chah M. Shen, Ph.D.
Director of Research and Development
Lang Dental Manufacturing Co., Inc.
P.O. Box 969, 175 Messner Dr.
Wheeling, IL 60090
847/215-6622
FAX: 847/215-6678
cshen@langdental.com

Appendix

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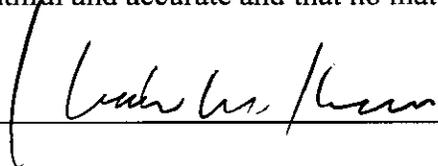
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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as the Director of Research & Development of Lang Dental Manufacturing Company Inc., at 175 Messner Dr., Wheeling, IL 60090, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)



Chah M. Shen

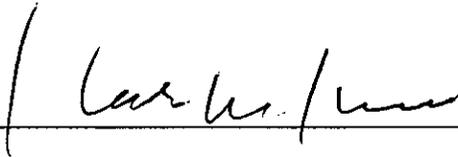
(Typed Name)

June 23, 2008

(Date)

PREMARKET NOTIFICATION STATEMENT

I certify that, in my capacity as the Director of Research & Development of Lang Dental Manufacturing Company Inc., 175 Messner Dr., Wheeling, IL 60090, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, excluding all patient identifiers, trade secret and confidential commercial information as defined in 21 CFR 20.61.



(Signature)

Chah M. Shen

(Typed Name)

June 23, 2008

(Date)

PRODUCT DESCRIPTION

Lang Dental Acrylic Primer is a high-quality, self-curing, 1-part system.

Paint Acrylic Primer liquid over original acrylic surface to which new acrylic will be added. Allow Acrylic Primer to dry. Add new acrylic.

Lang Dental Acrylic Primer is intended to be used as an acrylic bonding agent.

CONFIDENTIAL

LANG DENTAL ACRYLIC PRIMER COMPOSITION

Percentage by weight

1.	(b) (4)	[REDACTED]	[REDACTED]
2.	(b) (4)	[REDACTED]	[REDACTED] 3%
3.	(b) (4)	[REDACTED]	[REDACTED]
4.	(b) (4)	[REDACTED]	[REDACTED]

Total100.0000%

LANG DENTAL ACRYLIC PRIMER

(b)(4) Product Specs



**PACKAGE/LABELING SPECIFICATIONS
LANG DENTAL ACRYLIC PRIMER**

Product: 1-oz Bottle Lang Dental Acrylic Primer (30 ml)

Material: 30 ml Lang Dental Acrylic Primer liquid

Packaging: 1 x plain 1-oz Liquid cylinder
1 x chipboard 1-oz carton plain
2 x Acrylic Primer 30 ml label *1
1 x Lang Dental Acrylic Primer Direction Sheet *2

PACKAGE/LABELING SPECIFICATIONS

LANG DENTAL ACRYLIC PRIMER

*1

 	Lang Dental Mfg. Co., Inc. Wheeling, IL 60090-0969 www.LangDental.com Made in USA	Acrylic Primer
	Authorized Representative in EU: MediMark © Europe BP 2332, 38033 Grenoble Cedex 2 France	
WARNING: FLAMMABLE		Bonding Enhancer
Liquid & vapors can cause moderate irritation and sensitization. Close container tightly after use. Store in a cool, dry, well-ventilated location, away from sources of ignition and light. Contains: METHYL METHACRYLATE MONOMER, stabilized FLASH POINT: 52.7°F (11.5°C) NFPA, N PCA-HMIS #4-2F-3R-2		Promoteur de scellement
 F - Highly Flammable		Adhesivo intensificador
 Xi - Irritant		Haftkraftverstärker
		REF 1602 LDL 1602 R.3

*2 See Directions for Use Lang Dental Acrylic Primer

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Lang Dental Acrylic Primer

Indications for Use:

LANG DENTAL Acrylic Primer is intended for use as an acrylic bonding agent.

Prescription Use X
(21 CFR part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR part 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 _____

DIRECTIONS FOR USE LANG DENTAL ACRYLIC PRIMER

Acrylic Primer

Product Identification

Bonding enhancer

Package Contents

REF 1602 Net Vol. 30ml

Intended Purpose

This product is intended to be used as an acrylic bonding agent. When used as instructed, product is 100% effective.



Storage Conditions/Instructions

Keep away from heat, sparks and open flame. Keep container closed when not in use. Store in original container. Store between 36°F and 90°F (2°C and 32°C).



F - Highly Flammable

Operating/Handling Instructions

Liquid may cause skin irritation. Avoid contact with skin, eyes and clothing. Wear protective gloves, safety glasses with side shields or chemical splash goggles. Avoid prolonged breathing of vapors. Use with adequate ventilation. Do not smoke in the presence of open containers. See Material Safety Data Sheet for complete information. MSDS is available at www.langdental.com or by contacting manufacturer.



Xi - Irritant

Warning: flammable liquid. Contains: Methyl Methacrylate Monomer, Inhibited. Flash Point: 52.7°F (12°C), (T.C.C.) NFPA, NPCA-HMIS #: H-2,F-3, R-2.

Contraindications

Acrylic Primer is contraindicated for persons with allergies to chemicals.

**DIRECTIONS FOR USE
LANG DENTAL ACRYLIC PRIMER**

Other Materials/Equipment Needed

1. Brush

Instructions for Use

1. Paint Acrylic Primer liquid over original acrylic surface to which new acrylic will be added.
2. Allow Acrylic Primer to dry.
3. Add new acrylic.

Disposal

Dispose of unused material in accordance with local, state, and national legislation.

Warranty

Manufacturer warrants this product to be free from manufacturing defects for one year from date of purchase. Warranty is void if product is used for other than intended purpose or other than instructed.

Authorized Representative in EU:

MediMark[®] Europe
BP 2332
38033 Grenoble Cedex 2
France



Lang Dental Mfg. Co., Inc.
Wheeling, IL 60090-0969
www.LangDental.com
Made in USA
Ph 847-215-6622
Fax 847-215-6678

The LANG logo features the word 'LANG' in a bold, italicized, sans-serif font. A diagonal line strikes through the letters from the bottom left to the top right.

LDD 16 REV.2

CONFIDENTIAL

**COMPOSITION OF DEVICE CLAIMED EQUIVALENCY
LANG DENTAL ACRYLIC PRIMER**

LANG DENTAL ACRYLIC PRIMER COMPOSITION
FL-1642

Percentage by weight

1.	(b) (4)	
2.	(b) (4)	
3.	(b) (4)	
Total	100.0000%

LANG DENTAL ACRYLIC PRIMER

(b)(4)Product Specs

[REDACTED]

**PACKAGE/LABELING SPECIFICATIONS OF DEVICE CLAIMED
EQUIVALENCY**

LANG DENTAL ACRYLIC PRIMER

Product: 1-oz Bottle Lang Dental Acrylic Primer (30 ml)

Material: 30 ml Lang Dental Acrylic Primer liquid

Packaging: 1 x plain 1-oz Liquid cylinder
1 x chipboard 1-oz carton plain
2 x Acrylic Primer 30 ml label *1
1 x Lang Dental Acrylic Primer Direction Sheet *2

**PACKAGE/LABELING SPECIFICATIONS OF DEVICE CLAIMED
EQUIVALENCY**

LANG DENTAL ACRYLIC PRIMER

*1

 	Lang Dental Mfg. Co., Inc. Wheeling, IL 60090-0969 www.LangDental.com Made in USA	 Acrylic Primer Net Vol. 30ml
	Authorized Representative in EU: MediMark Europe BP 2332, 38033 Grenoble Cedex 2 France	
WARNING: FLAMMABLE		Bonding Enhancer
Liquid & vapors can cause moderate irritation and sensitization. Close container tightly after use. Store in a cool, dry, well-ventilated location, away from sources of ignition and light. Contains: METHYL METHACRYLATE MONOMER, stabilized FLASH POINT: 52.7°F (11.5°C) NFPA, N PCA-HMIS #H-2,F-3,R-2		Promoteur de scellement
 F - Highly Flammable		Adhesivo intensificador
 Xi - Irritant		Haftkraftverstärker
		REF 1602 LDL 1602 R.J

*2 See Directions for Use Lang Dental Acrylic Primer

INDICATIONS FOR USE OF DEVICE CLAIMED EQUIVALENCY

510(k) Number (if known):

Device Name: Lang Dental Acrylic Primer

Indications for Use:

LANG DENTAL Acrylic Primer is intended for use as an acrylic bonding agent.

Prescription Use X
(21 CFR part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR part 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 _____

**DIRECTIONS FOR USE
OF DEVICE CLAIMED EQUIVALENCY**

LANG DENTAL ACRYLIC PRIMER

Acrylic Primer

Product Identification

Bonding enhancer

Package Contents

REF 1602 Net Vol. 30ml

Intended Purpose

This product is intended to be used as an acrylic bonding agent. When used as instructed, product is 100% effective.

Storage Conditions/Instructions



Keep away from heat, sparks and open flame. Keep container closed when not in use. Store in original container. Store between 36°F and 90°F (2°C and 32°C).

Operating/Handling Instructions



F - Highly Flammable

Liquid may cause skin irritation. Avoid contact with skin, eyes and clothing. Wear protective gloves, safety glasses with side shields or chemical splash goggles. Avoid prolonged breathing of vapors. Use with adequate ventilation. Do not smoke in the presence of open containers. See Material Safety Data Sheet for complete information. MSDS is available at www.langdental.com or by contacting manufacturer.



Xi - Irritant

Warning: flammable liquid. Contains: Methyl Methacrylate Monomer, Inhibited. Flash Point: 52.7°F (12°C), (T.C.C.) NFPA, NPCA-HMIS #: H-2,F-3, R-2.

Contraindications

Acrylic Primer is contraindicated for persons with allergies to chemicals.

**DIRECTIONS FOR USE
OF DEVICE CLAIMED EQUIVALENCY**

LANG DENTAL ACRYLIC PRIMER

Other Materials/Equipment Needed

1. Brush

Instructions for Use

1. Paint Acrylic Primer liquid over original acrylic surface to which new acrylic will be added.
2. Allow Acrylic Primer to dry.
3. Add new acrylic.

Disposal

Dispose of unused material in accordance with local, state, and national legislation.

Warranty

Manufacturer warrants this product to be free from manufacturing defects for one year from date of purchase. Warranty is void if product is used for other than intended purpose or other than instructed.

Authorized Representative in EU:

MediMark® Europe
BP 2332
38033 Grenoble Cedex 2
France



Lang Dental Mfg. Co., Inc.
Wheeling, IL 60090-0969
www.LangDental.com
Made in USA
Ph 847-215-6622
Fax 847-215-6678



LDD 16 REV.2

CONFIDENTIAL

RATIONALE FOR SUBSTANTIAL EQUIVALENCY

Lang Dental Acrylic Primer has been manufactured by Lang Dental Manufacturing Co., Inc. since the early 1960's as a pre-amendment device.

Lang Dental Acrylic Primer is a self-curing, 1-part system.

Paint Acrylic Primer liquid over original acrylic surface to which new acrylic will be added. Allow Acrylic Primer to dry. Add new acrylic.

Lang Dental Acrylic Primer is intended to be used as an acrylic bonding agent.

The product contains (b)(4) and (b)(4). It is packaged in one ounce bottle.

Lang Dental has been purchasing acrylic lacquer (methyl methacrylate monomer and polymethyl methacrylate polymer) and added to methyl methacrylate monomer and hydroquinone in house to produce Acrylic Primer.

(b)(4)

The proposed new Acrylic Primer contains (b)(4)

(b)(4)

(b)(4) having good stability to heat and UV light and excellent resistance to hydrolysis. It can be used to provide (b)(4) for a wide range of resins and polymer. (b)(4) is also present in the Lang Dental Resin A97 powder, premarket notification K972553 dated 11/13/1997.

(b)(4) It evaporates easily at room temperature and has a HMIS hazardous material identification system health rating of 1 (slight hazard).

Both acrylic primer materials were tested and no significant differences can be found between these two materials (see below).

Lang Dental Acrylic Primer

Original Lang Dental Acrylic Primer

Materials

(b)(4) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Curing method

Self-curing

Self-curing

Indications for use

Acrylic bonding agent

Acrylic bonding agent

Curing Time, minutes

1.5

1.5

Color

Clear

Clear

Extraneous Matter

None detected

None detected

BIOCOMPATIBILITY TESTING STATEMENT

Lang Dental Acrylic Primer and the original Lang Dental Acrylic Primer are similar in use and formulation. The formulation does not contain any new or non-conventional chemicals new biocompatibility testing is unwarranted.



COVER SHEET MEMORANDUM

From: Reviewer Name _____
 Subject: 510(k) Number K081981/81
 To: The Record _____

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		X	
Nanotechnology			X

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number 21 CFR 872.3760 Class* II Product Code EBI
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____
 (Branch Chief) [Signature] (Branch Code) [Signature] (Date) 11/14/08

Final Review: _____
 (Division Director) [Signature] (Date) 11-17-08



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional**

K081981

Date: 14 November 2008

To: The Record

Office: ODE

From: Nicholas W. Werner, Biomedical Engineer

Division: DAGID

510(k) Holder: Lang Dental Mfg. Co., Inc., Wheeling, Illinois

Device Name: *Lang Dental Acrylic Primer* (K081981)

Contact: Dr. Chah Shen

Phone: 1-847-215-6622

Fax: 1-847-215-6676

Email: cshen@langdental.com

I. Purpose and Submission Summary

Lang Dental Mfg. Co., Inc., of Wheeling, Illinois, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *Lang Dental Acrylic Primer*, an acrylic bonding agent. *Lang Dental Acrylic Primer* is a prescription Class II medical device regulated under 21 CFR 872.3760 as a "Denture relining, repairing, or rebasing resin." The *Lang Dental Acrylic Primer* is listed under product code EBI.

The submission for *Lang Dental Acrylic Primer* consists of device description, material safety data sheets, draft labeling, indications and directions for use, and a substantial equivalence discussion. The submission claims substantial equivalence to *Lang Dental Acrylic Primer*, a pre-amendment device.

The information submitted by Lang Dental Mfg. Co., Inc., demonstrates that *Lang Dental Acrylic Primer* (K081981) has the same indications and technological characteristics as a legally marketed device. *Lang Dental Acrylic Primer* is substantially equivalent (SE) to a predicate denture relining, repairing, or rebasing resin.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary		x	
510(k) Statement	x		
Standards Form			x

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?		x	
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		x	

Lang Dental Acrylic Primer is a self-curing, 1-part acrylic bonding system. The system is comprised of a liquid polymer.

Lang Dental Acrylic Primer is applied over an original acrylic surface to help prepare the surface for the addition of new acrylic.

Lang Dental Acrylic Primer has a chemical composition as follows:

Component	CAS Number	% Weight
(b)(4)	80-62-6	51.7368
(b)(4)	67-64-1	34.4913
(b)(4)	9011-14-7, 84-66-2	13.5722
(b)(4)	128-37-0	0.1997

(b)(4)

Lang Dental Acrylic Primer, K081981, Lang Dental MFG. Co., Inc.

IV. Indications for Use

Lang Dental Acrylic Primer is intended for use as an acrylic bonding agent when adding new acrylic to existing denture base acrylic.

V. Labeling

The proposed labeling consists of the intended purpose, storage conditions, handling instructions, contraindications, instructions for use, and warranty information. Also included are the package contents and a product identification. The instructions are adequate for use and all other relevant information is available.

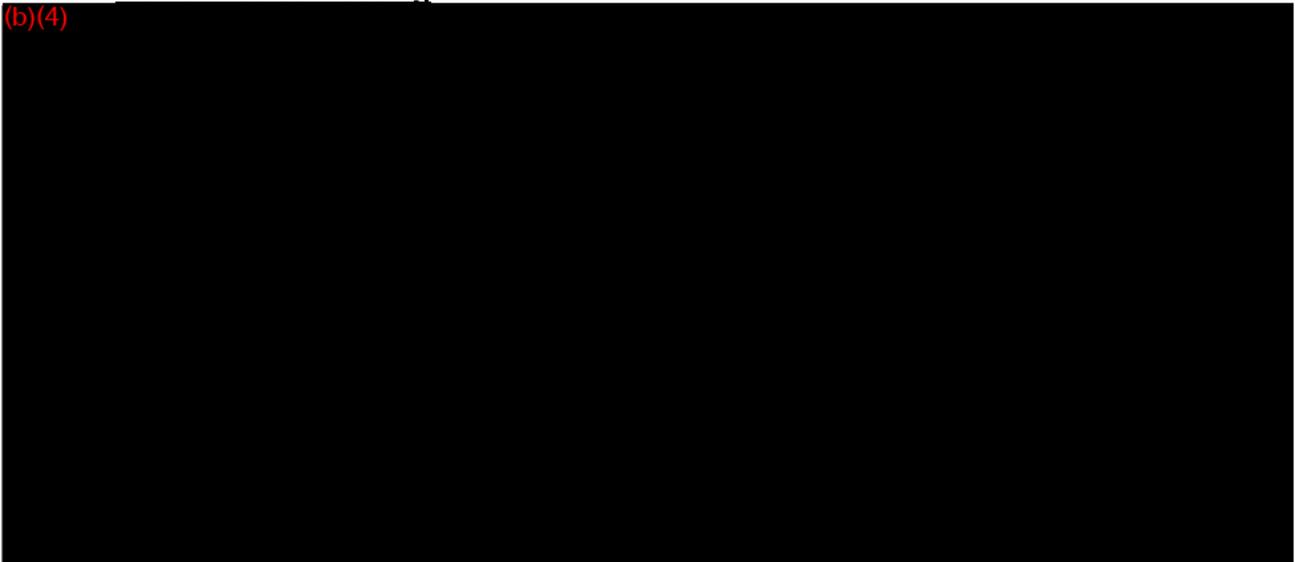
The shelf life is given to be one year from the date of manufacture (see correspondence dated 11/12).

VI. Biocompatibility

The chemical formulation for *Lang Dental Acrylic Primer* is similar to that of the predicate device *Lang Dental Acrylic Primer*, a pre-amendment device. No issues of biocompatibility have been reported with the predicate device and there are no unconventional or new chemicals within the formulation of the proposed device.

VII. Performance Testing

(b)(4)



VIII. Predicate Device Comparison

Products to Which this Device is Compared (510(K) Number If Known):

Lang Dental Acrylic Primer (Pre-amendment)

Lang Dental Acrylic Primer is comparable to another legally marketed priming agent on the market. The major difference between *Lang Dental Acrylic Primer* and its predicate priming agent is the selection and relative percentage of its components. (b)(4)



(b)(4)

(b)(4)

IX. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	x		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	x		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	x		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

Lang Dental Acrylic Primer, K081981, Lang Dental MFG. Co., Inc.

7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The intended use for this device and IFUS included in this submission have not changed from the direct predicate device. No new technological characteristics have been introduced in *Lang Dental Acrylic Primer* that could affect the device's safety or effectiveness.

The formulation of *Lang Dental Acrylic Primer* is the very similar to the previously cleared predicate devices and raises no biocompatibility concerns. (b)(4)

X. Contact History

On September 17, the reviewer contacted the applicant via phone to address issues with the submission. The reviewer requested a more specific IFUS, the addition of a shelf life to the directions for use, and performance specification testing that includes (b)(4). A follow-up email was sent to the applicant that outlined these requests.

The applicant responded the same day via email to say that the IFUS and directions for use will be changed and that an outside lab will be contacted for the testing.

On September 23, the applicant contacted the reviewer via email with the exact changes that will be made to the submission regarding the IFUS and directions for use. The applicant also stated that a lab was contacted regarding the testing requested. A protocol was provided, as given by the lab. Since the protocol stated that the testing will take 4-5 weeks, the document will be placed on telephone hold. The document requires the submission of a new IFUS, updated labeling, and requested performance testing to be removed from hold.

On September 30, the applicant contacted the reviewer via email to provide an additional test protocol for review and approval. This test protocol for the (b)(4) was adequate for inclusion.

On November 12, the applicant contacted the reviewer via mail to provide the originally requested additional information, thus removing the hold. The applicant provided testing for (b)(4). Also included was a revised Indications for Use Statement and a revised Directions for Use that contained the shelf life of the product.

Lang Dental Acrylic Primer, K081981, Lang Dental MFG. Co., Inc.

XI. Recommendation

Regulation Number: 21 CFR 872.3760

Regulation Name: Denture relining, repairing, or rebasing resin

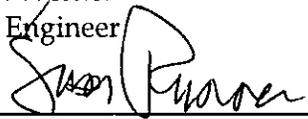
Regulatory Class: Class II

Product Code: EBI



Reviewer
Nicholas W. Werner
Biomedical Engineer

11/14/08
Date



Branch Chief
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

11/14/08
Date



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

TELEPHONE HOLD MEMORANDUM
K081981

Date: 23 September 2008

To: The Record

Office: ODE

From: Nicholas W. Werner, Biomedical Engineer

Division: DAGID

510(k) Holder: Lang Dental Mfg. Co., Inc., Wheeling, Illinois

Device Name: *Lang Dental Acrylic Primer* (K081981)

Contact: Dr. Chah Shen

Phone: 1-847-215-6622

Fax: 1-847-215-6676

Email: cshen@langdental.com

I. Purpose and Submission Summary

Lang Dental Mfg. Co., Inc., of Wheeling, Illinois, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *Lang Dental Acrylic Primer*, an acrylic bonding agent. *Lang Dental Acrylic Primer* is a prescription Class II medical device regulated under 21 CFR 872.3760 as a "Denture relining, repairing, or rebasing resin." The *Lang Dental Acrylic Primer* is listed under product code EBI.

The submission for *Lang Dental Acrylic Primer* consists of device description, material safety data sheets, draft labeling, indications and directions for use, and a substantial equivalence discussion. The submission claims substantial equivalence to *Lang Dental Acrylic Primer*, a pre-amendment device.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary		x	
510(k) Statement	x		
Standards Form			x

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?		x	
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		x	

Lang Dental Acrylic Primer is a self-curing, 1-part acrylic bonding system. The system is comprised of a liquid polymer.

Lang Dental Acrylic Primer is applied over an original acrylic surface to help prepare the surface for the addition of new acrylic.

Lang Dental Acrylic Primer has a chemical composition as follows:

Component	CAS Number	% Weight
(b)(4)	80-62-6	51.7368
(b)(4)	67-64-1	34.4913
(b)(4)	9011-14-7, 84-66-2	13.5722
(b)(4)	128-37-0	0.1997

(b)(4)

IV. Indications for Use

Lang Dental Acrylic Primer is intended for use as an acrylic bonding agent.

V. Contact History/Telephone Hold

On September 17, the reviewer contacted the applicant via phone to address issues with the submission. The reviewer requested a more specific IFUS, the addition of a shelf life to the directions for use, and performance specification testing that includes a (b)(4) [REDACTED]. A follow-up email was sent to the applicant that outlined these requests.

The applicant responded the same day via email to say that the IFUS and directions for use will be changed and that an outside lab will be contacted for the testing.

On September 23, the applicant contacted the reviewer via email with the exact changes that will be made to the submission regarding the IFUS and directions for use. The applicant also stated that a lab was contacted regarding the testing requested. A protocol was provided, as given by the lab. Since the protocol stated that the testing will take 4-5 weeks, the document will be placed on telephone hold. The document requires the submission of a new IFUS, updated labeling, and requested performance testing to be removed from hold.



Reviewer
Nicholas W. Werner
Biomedical Engineer

9/23/08
Date



Branch Review
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

9/24/08
Date

Werner, Nicholas W

From: Werner, Nicholas W
Sent: Tuesday, September 23, 2008 4:01 PM
To: 'Chah Shen'
Subject: RE: Lang Dental Acrylic Primer (K081981) Additional Information Request

Dr. Shen,

Thank you for providing the changes you will be making to the submission. Those responses do adequately address the issues brought up with the submission. The test protocol seems appropriate for the testing indicated and feel free to begin whenever you are ready. Since the protocol indicates that the testing will take 4-5 weeks upon the receipt of the materials, I will be placing this document on telephone hold. Therefore, when the testing is completed, please send all the information in hard copy to the Document Mail Center. Please be sure to reference the 510(k) number (K081981) to ensure proper routing. I would be happy to answer any questions or look over any information before the document is removed from hold to see if the requested responses address all of my concerns.

Please feel free to contact me at any point with any questions or concerns.

Thank you,

Nicholas W. Werner

Biomedical Engineer/Reviewer

FDA/ODE/DAGID/DEDB

Phone: 240-276-1374

Fax: 240-276-3789

Mail: HFZ-480

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From: Chah Shen [mailto:cshen@langdental.com]
Sent: Tuesday, September 23, 2008 3:24 PM
To: Werner, Nicholas W
Cc: Chah Shen
Subject: RE: Lang Dental Acrylic Primer (K081981) Additional Information Request

9/23/08

Dear Mr. Nicholas Werner,

We will revise our Indications for Use per your request to indicate that the product is used as an acrylic bonding agent when adding new acrylic to existing denture base acrylic.

We will revise our Directions for Use per your request to include Shelf life: One year from date of manufacture under Storage Conditions/Instructions.

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Best regards,

Chah Shen, Ph.D.
Director of Research & Development
Lang Dental Manufacturing Co., Inc.
175 Messner Drive
Wheeling, IL 60090
E-mail: chahshen@hotmail.com
Telephone 847 215-6622
FAX 847 215-6678

-----Original Message-----

From: Werner, Nicholas W [mailto:nicholas.werner@fda.hhs.gov]
Sent: Wednesday, September 17, 2008 10:03 AM
To: Chah Shen
Subject: Lang Dental Acrylic Primer (K081981) Additional Information Request

Dr. Shen,

As per our conversation today, the following issues should be addressed with your submission:

- (b)(4) Testing [Redacted]
- [Redacted]

[REDACTED] (b)(4) [REDACTED]
[REDACTED] Testin
[REDACTED] g
[REDACTED]

Please feel free to call or email me with any questions or concerns you have with the issues addressed above.

Thank you,

Nicholas W. Werner
Biomedical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
Phone: 240-276-1374
Fax: 240-276-3789
Mail: HFZ-480



Protecting and Promoting Public Health

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I am using the free version of SPAMfighter for private users.
It has removed 125 spam emails to date.
Paying users do not have this message in their emails.
Try [SPAMfighter](#) for free now!

I am using the free version of SPAMfighter for home users.
SPAMfighter has removed 0 spam emails to date.
Paying users do not have this message in their emails.
Try [SPAMfighter](#) for free now!



November 13, 2008

LANG DENTAL MFG. CO., INC.
175 MESSNER DR.
WHEELING, ILLINOIS 60090-0969
UNITED STATES
ATTN: CHAH M. SHEN

510k Number: K081981

Product: LANG DENTAL ACRYLIC PRIMER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

November 10, 2008

To: Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA CDRH DMC

NOV 12 2008

Attention: Document Control Clerk

Received

RE: 510(k) Notification
K081981 Lang Dental Acrylic Primer
Additional Information

K-34

Concerning your request on September 17, 2008, attached please find the following information in duplicate:

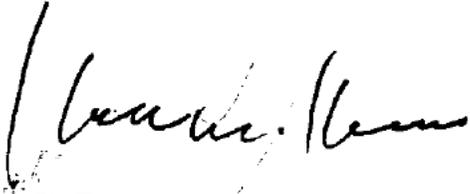
We have revised Indications for Use, Product Description and Direction for Use pages and attached (see Attachments I, II & III).

(b) (4)
[Redacted]

(b)(4) Testing
[Redacted]

If you have any questions or require additional information please call me at (847) 215-6622.

Sincerely,



Chah M. Shen, Ph.D.
Director of Research and Development
Lang Dental Manufacturing Co., Inc.
P.O. Box 969, 175 Messner Dr.
Wheeling, IL 60090
847/215-6622
FAX: 847/215-6678
cshen@langdental.com

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Lang Dental Acrylic Primer

Indications for Use:

LANG DENTAL Acrylic Primer is intended for use as an acrylic bonding agent when adding new acrylic to existing denture base acrylic.

Prescription Use X
(21 CFR part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR part 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 _____

PRODUCT DESCRIPTION

Lang Dental Acrylic Primer is a high-quality, self-curing, 1-part system.

Paint Acrylic Primer liquid over original acrylic surface to which new acrylic will be added. Allow Acrylic Primer to dry. Add new acrylic.

Lang Dental Acrylic Primer is intended to be used as an acrylic bonding agent when adding new acrylic to existing denture base acrylic.

Acrylic Primer

Product Identification

Bonding agent

Package Contents

REF 1602 Net Vol. 30ml

Intended Purpose

This product is intended to be used as an acrylic bonding agent when adding new acrylic to existing denture base acrylic. When used as instructed, product is 100% effective.

Storage Conditions/Instructions

Liquid and vapors can cause moderate irritation and sensitization. Close container tightly after use. Store in original container in a cool, dry, well-ventilated location away from sources of ignition and light. Shelf life: One year from date of manufacture.

Operating/Handling Instructions



F - Highly Flammable Xi - Irritant

Liquid may cause skin and eye irritation. Avoid contact with skin, eyes and clothing. Wear protective gloves, safety glasses with side shields or chemical splash goggles. Avoid prolonged breathing of vapors. May cause respiratory tract irritation. Use with adequate ventilation. Do not smoke in the presence of open containers. See Material Safety Data Sheet for complete information. MSDS is available at www.langdental.com or by contacting manufacturer.

Warning: Flammable liquid and vapor. Vapor may cause flash fire. Contains: Methyl Ethyl Ketone. Flash Point: 16°F (-9°C) (T.C.C.); NFPA, #: H-1, F-3, R-0; HMIS #: H-2, F-3, R-0.

Contraindications

Acrylic Primer is contraindicated in patients with allergies to chemicals.

Other Materials/Equipment Needed

Brush

Instructions for Use

1. Paint Acrylic Primer liquid over original acrylic surface to which new acrylic will be added.
2. Allow Acrylic Primer to dry.
3. Add new acrylic.

Disposal

Dispose of unused material in accordance with local, state and national legislation.

Warranty

Manufacturer warrants this product to be free from manufacturing defects for one year from date of purchase. Warranty is void if product is used for other than intended purpose or other than instructed.

CE **Authorized Representative in EU:**
MediMark® Europe
BP 2332 38033 Grenoble, Cedex 2
France

LANG

Lang Dental Mfg. Co., Inc.
Wheeling, IL 60090-0969
www.LangDental.com
Made in USA
Ph 847-215-6622
Fax 847-215-6678

Lang Dental Acrylic Primer Performance Specification K081981

(b) (4)



Werner, Nicholas W

From: Werner, Nicholas W
Sent: Tuesday, September 30, 2008 3:16 PM
To: 'Chah Shen'
Subject: RE: Lang Dental Acrylic Primer Testing 510(k) K081981

Dr. Shen,

(b) (4)

Thank you,

Nicholas W. Werner

Biomedical Engineer/Reviewer

FDA/ODE/DAGID/DEDB

Phone: 240-276-1374

Fax: 240-276-3789

Mail: HFZ-480

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From: Chah Shen [mailto:cshen@langdental.com]
Sent: Tuesday, September 30, 2008 2:59 PM
To: Werner, Nicholas W
Cc: Chah Shen
Subject: FW: Lang Dental Acrylic Primer Testing 510(k) K081981

9/30/08

Dear Mr. Nicholas Werner,

(b) (4)

Many thanks in advance.

Best regards,

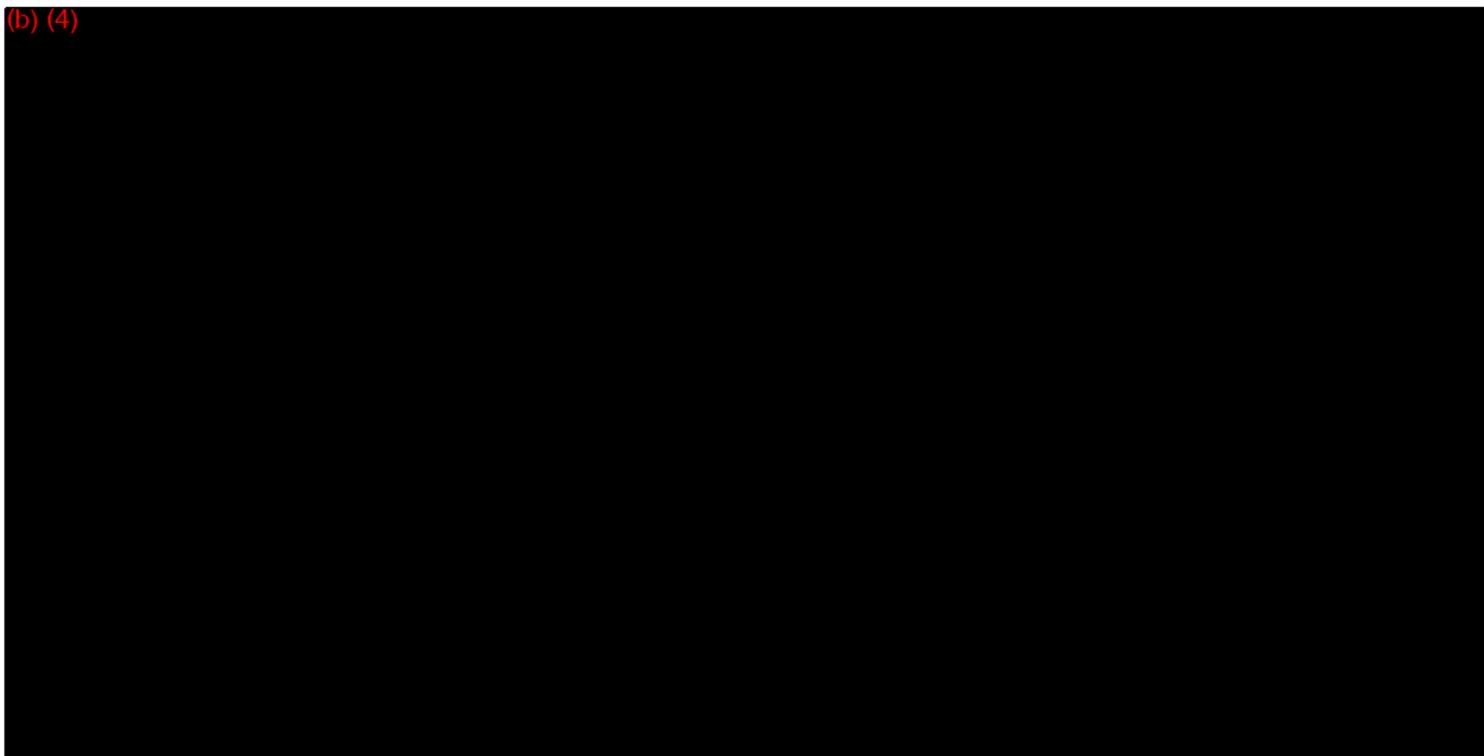
Chah Shen, Ph.D.
Director of Research & Development
Lang Dental Manufacturing Co., Inc.
175 Messner Drive
Wheeling, IL 60090
E-mail: chahshen@hotmail.com
Telephone 847 215-6622
FAX 847 215-6678

-----Original Message-----

From: Ron Yapp [mailto:ron@dentaladvisor.com]
Sent: Tuesday, September 30, 2008 10:29 AM
To: 'Chah Shen'
Subject: RE: Lang Dental Acrylic Primer Testing

Dear Chah,

(b) (4)



Thanks

Ron

11/14/2008