



USER: COLMES, JERI R (jrc)

FOLDER: K945462 - 289 pages (FOI:08000646)

COMPANY: BLOCK DRUG COMPANY, INC.
(BLOCDRUGA)

PRODUCT: CARBOXYMETHYLCELLULOSE SODIUM
OR POLYVINYL METHYLETHER MALEIC
ACID CALCIUM-SODIUM (KOT)

SUMMARY: Product: SUPER POLI-GRIP DENTURE
ADHESIVE CREAM

DATE REQUESTED: Tue Aug 11 24:00:00 2009

DATE PRINTED: Mon Aug 24 14:25:03 2009

Note: Releasable Version

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L945463

DEC 20 1994

510(k) Summary

SUPER POLI-GRIP DENTURE ADHESIVE CREAM

0346

510(k) Summary
SUPER POLI-GRIP DENTURE ADHESIVE CREAM

- [1] Submitter's name: BLOCK DRUG COMPANY, INC.
- Address: 257 Cornelison Ave.
 Jersey City, NJ 07302-9988
- Telephone Number: (201) 434-3000 Ext. 1794
 Fax Number: (201) 332-2362
- Contact Person: Filomena King
- Date Prepared: November 1, 1994
- [2] Name of Device: Super Poli-Grip
- Common Name: Denture Adhesive
- [3] Identification of device to which substantial equivalence
 is claimed.
- Super Poli-Grip® Denture Adhesive Cream (#K862876)
 Block Drug Company, Inc.
 257 Cornelison Ave.
 Jersey City, NJ 07302
- Fixodent® Denture Adhesive Cream
 Procter & Gamble
 Cincinnati, Ohio 45202

0247

510(k) Summary
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

[4] Description of device that is the subject of the pre-market notification submission:

How the device functions:

Super Poli-Grip® is a cream product which is applied to the base of a denture before the denture is inserted in the mouth to improve denture retention and comfort.

Basic scientific concept that form the basis for the device:

The Poli-Grip® Denture Adhesive is a cream that derives retentive properties from carboxymethylcellulose and polyvinylmethylether maleic acid salt. These adhesives spread between the denture and tissue surface, excluding air. Retention is achieved through the increase in adhesion properties that develop when adhesive salts swell in the presence of saliva.

Significant physical characteristics:

Poli-Grip® Denture Adhesive Cream is a smooth, homogenous pinkish-red cream with a pleasant flavor.

Performance characteristics:

The Poli-Grip® Denture Adhesive Cream is specially formulated to form a tight seal and provide a firm hold of dentures. The improved denture retention afforded by the Poli-Grip® product enables the consumer to masticate all types of food with ease and comfort.

Device design and Device materials used:

The Poli-Grip® Denture Adhesive Cream is a ready to use product composed of adhesives, hydrocarbon vehicle base, preservative, flavorant and colorant.

Device physical properties:

Super Poli-Grip® Denture Adhesive Cream is a smooth, homogeneous cream with a characteristic flavor.

510(k) Summary
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

[5] Intended use:

Super Poli-Grip® is a cream product which is applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

Patient population:

Patients which may require better retention and comfort of ill-fitting dentures.

Difference between Super Poli-Grip® and the substantially equivalent product:

Minor formula differences exist between the Super Poli-Grip® Denture Adhesive Cream and the substantially equivalent products. These differences do not detract from the ability of the product to perform as a denture adhesive, to aid in the retention and comfort of dentures.

Why the difference does not effect the safety and effectiveness of the device.

There are no critical differences between Super Poli-Grip® Denture Adhesive Cream and the substantially equivalent products. The oral toxicity, oral mucosal irritation and eye irritancy of the Super Poli-Grip® product have been determined. The Super Poli-Grip® product has demonstrated a satisfactory animal safety profile. Additionally, efficacy data indicates that the Super Poli-Grip product is highly efficacious with no significant difference in performance with a predicate Super Poli-Grip® and a currently marketed product.

[6] How they compare in technology, (design, material, chemical composition, or energy source) in [3]:

There is no significant difference between the products. While product formulae may vary somewhat, all provide good denture retention and comfort to the consumer.

[7] Safety and Efficacy Information

Safety

The safety of Super Poli-Grip® Denture Adhesive Cream has been determined through animal safety studies. The product has demonstrated a satisfactory animal safety profile.

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510(k) Summary
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

A summary of the acute oral toxicity, eye irritation and oral mucosal irritation studies conducted on Super Poli-Grip® Denture Adhesive Cream follows.

Acute Oral Toxicity

Five male and five female Sprague-Dawley rats were employed for this study. After an acclimation period of five days, all animals were fasted overnight and subsequently dosed orally by gavage at a dose level of 5 g/kg body weight. The animals were observed for pharmacotoxic signs and mortality during a 15 day observation period. All animals were subjected to a gross necropsy examination at study termination.

All animals survived the study. No product related abnormalities were noted in any of the animals at terminal necropsy. The oral LD₅₀ was greater than 5 grams per kilogram.

Primary Eye Irritation Study

The potential primary eye irritation of the product was evaluated using six New Zealand White rabbits. The right eyes of three rabbits were treated with the test substance and remained unrinsed. The remaining three rabbits were treated with the test substance and then irrigated with 20 ml of lukewarm tap water approximately four seconds after test article instillation. The untreated contralateral eye of each rabbit served as a control. Treated and untreated eyes were examined and ocular irritation was scored according to the Draize method at 24, 48 and 72 hours after test article instillation.

The maximum mean primary eye irritation score in non-rinsed and rinsed eyes was found to be 2.0/110.0 and 1.3/110.0 respectively. Under conditions of this study, the product is classified as minimally irritating to the unrinsed and rinsed eye of the rabbit.

Oral Mucosal Irritation

One group of five male Sprague-Dawley rats was administered the product by four applications to the oral mucosa each day for four days. Prior to each application, the test sites were examined and scored. Following cessation of treatment the rats were examined and scored once daily for three days.

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510(k) Summary
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

There was no irritation to the oral mucosa observed in any of the five animals treated during the course of the study. The mean oral irritation score was 0/6.0. Under the conditions of this study, Super Poli-Grip® Denture Adhesive Cream is considered to be non-irritating to the oral mucosa.

Efficacy

The efficacy of Super Poli-Grip® Denture Adhesive Cream, as for any other denture adhesive product, is based upon the products ability to improve denture retention and comfort. Testing has been conducted to evaluate the proposed product's efficacy versus both Super Poli-Grip 510(k) #K862876 and the currently marketed Fixodent® product.

A Shear Strength study was conducted on the proposed Super Poli-Grip® versus the 510(k) #K862876 formula. It is apparent that a greater force is required to separate the plates treated with the proposed denture adhesive. Test results indicate that at the very least, the products evaluated have substantially equivalent adhesion characteristics.

The substantial equivalence in efficacy of the proposed product to that of the currently marketed Fixodent® product has also been evaluated. Consumers were provided with blinded product samples, label use directions and a questionnaire. The consumers (all regular Fixodent® users) were asked to use each of the adhesives and to complete and return the questionnaire which included various product performance related questions.

The results of this consumer test indicate that product performance for the proposed Super Poli-Grip® product is at least equivalent to that of Fixodent®, even among Fixodent® users. The proposed product demonstrates equivalent to superior performance versus Fixodent® for both denture retention and comfort.

Additional testing has been conducted to demonstrate equivalence in efficacy of the proposed adhesive to that of Fixodent®. A clinical study was conducted to demonstrate substantial equivalence between the proposed product and Fixodent® in their abilities to provide a significant improvement in the biting and chewing abilities of edentulous patients as demonstrated by bite force measurements and to examine adverse effects.

510(k) Summary
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

The electronic strain gauge technique was used in this study. Study results show that the application of the test materials significantly improved the bite force values for the subjects at all times intervals versus baseline. This is a desired benefit to the subject. The chewing and biting forces needed for mastication and cutting are greatly exceeded by the forces generated during this study for both test materials. No statistical nor clinical differences exist between the proposed Super Poli-Grip® and Fixodent® Denture Adhesives.



DEC 20 1994

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Filomena King
Regulatory Affairs Specialist
Block Drug Company, Incorporated
257 Cornelison Avenue
Jersey City, New Jersey 07302-3198

Re: K945462
Super Poli-Grip® Denture
Adhesive Cream
Regulatory Class: I
Product Code: KOT
Dated: November 1, 1994
Received: November 7, 1994

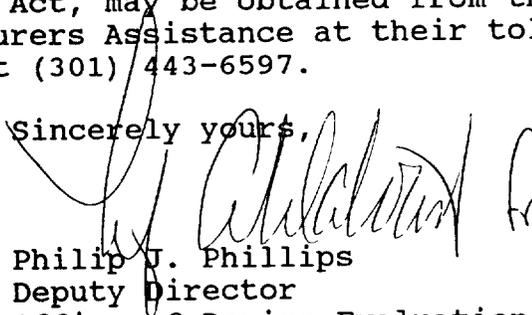
Dear Ms. King:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A Substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Device: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff, (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health



510(K) ROUTE SLIP

510(k) NUMBER K945462 PANEL DE DIVISION DGRD BRANCH DEDB

TRADE NAME SUPER POLI-GRIP DENTURE ADHESIVE CREAM

COMMON NAME DENTURE ADHESIVE

PRODUCT CODE _____

APPLICANT BLOCK DRUG CO., INC.

SHORT NAME BLOCDRUG

CONTACT FILOMENA KING

DIVISION _____

ADDRESS 2149 HARBOR AVENUE

MEMPHIS, TN 38113

PHONE NO. (____) ____-____

FAX NO. (____) ____-____

MANUFACTURER BLOCK DRUG CO., INC.

REGISTRATION NO. 1020379

DATE ON SUBMISSION 01-NOV-94

Poranich 12/15/94
DATE DUE TO 510(K) STAFF 21-JAN-95

DATE RECEIVED IN ODE 07-NOV-94

DATE DECISION DUE 05-FEB-95

DECISION _____

DECISION DATE DEC 20 1994

Jerry

Tier 1 review

Please expedite

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Memorandum

Date _____
 From REVIEWER(S) - NAME(S) GERALD SHIPPS
 Subject 510(k) NOTIFICATION K945462
 To THE RECORD

It is my recommendation that the subject 510(k) Notification:

(A) Is substantially equivalent to marketed devices.

(B) Requires premarket approval. NOT substantially equivalent to marketed devices.

(C) Requires more data.

(D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

A 510(k) summary of safety and effectiveness, or

A 510(k) statement that safety and effectiveness information will be made available

The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

Predicate Product Code w/panel and class:

No Confidentiality

76 KOT, 872.3490, class I

Confidentiality for 90 days

Additional Product Code(s) w/Panel (optional):

Continued Confidentiality exceeding 90 days

REVIEW: [Signature]
(BRANCH CHIEF)

DEDB
BRANCH CODE

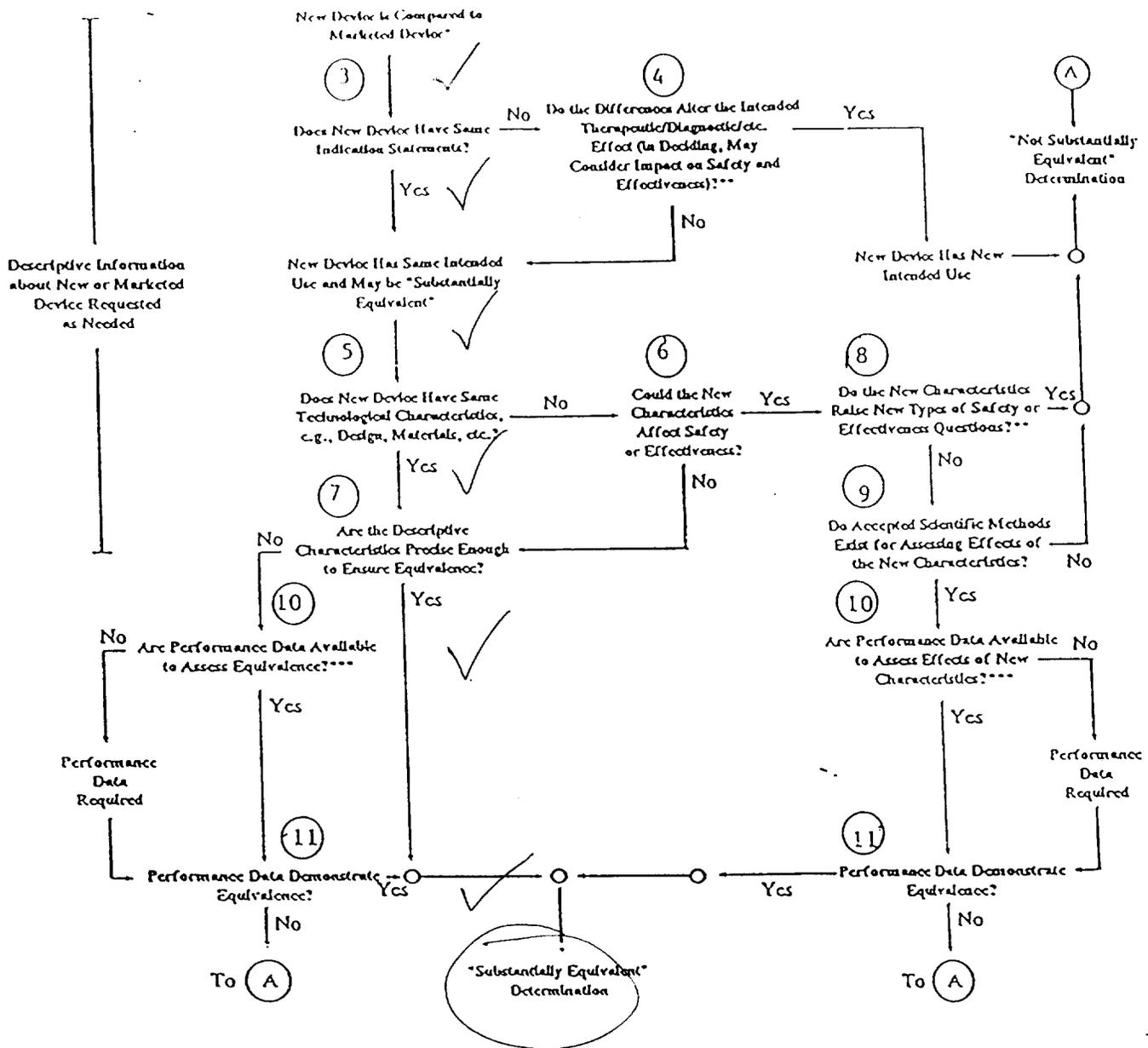
12/19/94
(DATE)

FINAL REVIEW: [Signature]
(DIVISION DIRECTOR)

RR 12/19/94
(DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

K 945462 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

DGRD PILOT /
DEDB

REVIEWER: GERALD SHIPPS DIVISION/BRANCH: DEDB

TRADE NAME: SUPER POLY-GRIP DENTURE ADHESIVE CREAM COMMON NAME: DENTURE ADHESIVE - CARBOXYMETHYLCELLULOSE

PRODUCT TO WHICH COMPARED: SUPER POLY-GRIP DENTURE ADHESIVE CREAM (K862876)
(510(k) NUMBER IF KNOWN)

YES | (NO)

- 1. IS PRODUCT A DEVICE? | - IF NO STOP
- 2. DEVICE SUBJECT TO 510(k)? | - IF NO STOP
- 3. SAME INDICATION STATEMENT? | - IF YES GO TO 5
- 4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? | - IF YES STOP - NE 
- 5. SAME TECHNOLOGICAL CHARACTERISTICS? | - IF YES GO TO 7
- 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? | - IF YES GO TO 8
- 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? | - IF NO GO TO 10 - IF YES STOP - SE 
- 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? | - IF YES STOP - NE 
- 9. ACCEPTED SCIENTIFIC METHODS EXIST? | - IF NO STOP - NE 
- 10. PERFORMANCE DATA AVAILABLE? | - IF NO REQUEST DATA
- 11. DATA DEMONSTRATE EQUIVALENCE? | 

 NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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Document: K945462
Device: Super Poly-Grip Denture Adhesive Cream
Classification: Class I
Regulation Number: 21CFR 872.3490 (76KOT)
Product To Which Compared:
Super Poly-Grip Denture Adhesive Cream (K862876)
Submitted by: Block Drug Company, Incorporated
Jersey City, New Jersey
Date Document Received in ODE: 11/07/94
Date Document Received by Reviewer: 12/01/94
Division Due Date: 1/20/95

Intended Use:

Super Poly-Grip Denture Adhesive Cream (Super Poly-Grip) is a combination carboxymethylcellulose sodium and polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive, intended to be applied to the base of a denture before it is inserted in a patient's mouth, to improve denture retention and comfort.

Analysis:

The Block Drug Company (BDC) Super Poly-Grip has the same intended use and is similar in composition to the original Super Poly-Grip Denture Adhesive Cream (original Super Poly-Grip) determined as SE under K862876. Both devices are intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort. They each contain (b)(4) hydrocarbon vehicle bases ((b)(4) petrolatum, (b)(4) mineral oil), (b)(4) carboxymethylcellulose sodium, and salts of polyvinylmethylether maleic acid ((b)(4) Super Poly-Grip and (b)(4) original Super Poly-Grip) which serve as adhesives. Both products contain (b)(4) (b)(4).

There are minor formulation differences between Super Poly-Grip and original Super Poly-Grip. The colorants are different (Super Poly-Grip contains (b)(4) colorants (b)(4) (b)(4) (b)(4) whereas original Super Poly-Grip contains (b)(4) colorants (b)(4) (b)(4) (b)(4)). Super Poly-Grip contains (b)(4) (b)(4) and (b)(4) flavorant (equal parts of spray-dried peppermint and spray-dried spearmint, in (b)(4) (b)(4)), but original Super Poly-Grip does not. Both flavorants used in Super Poly-Grip are composed of modified food starch, spearmint oil, and proprietary ingredients specified by the supplier (b)(4) (b)(4) to be approved for use by FDA regulation. The original Super Poly-Grip contains (b)(4) (b)(4) but Super Poly-Grip does not.

Animal studies of Super Poly-Grip revealed: 1)no product related abnormalities in acute oral toxicity; 2)the product was minimally irritating to rinsed and unrinsed eyes in primary eye irritation; and 3)no irritation in oral mucosal irritation. Shear strength

testing revealed similar results for Super Poly-Grip and the original device (Super Poly-Grip: (b)(4) and original Super Poly-Grip: (b)(4)).

Recommendation:

Based upon the information provided by BDC, Super Poly-Grip Denture Adhesive Cream is substantially equivalent to previously marketed denture adhesives, such as the original Super Poly-Grip Denture Adhesive Cream marketed under K862876, in terms of intended use, technological characteristics, safety and effectiveness.

Reviewer: Gerald Shipps Date: 12/13/94
Gerald Shipps

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PILOT Evaluation Staff Checklist
for Premarket Notifications (510(k)s)

Device Trade Name: <i>Super Pole Grip Dental Adhesive</i>		K#: <i>K945462</i>	
Submitter Name: <i>Block Drug Co., Inc</i>			
Date Received: <i>NOV 17 1994</i>			
90 Day Due Date: <i>20 Jan 95</i>			
Review Tier (circle one): <input checked="" type="radio"/> 1 2 3			
Question		Yes	No
A.	Is the product a device?	✓	
B.	Is the device exempt from 510(k)?		✓
C.	Expedited Review Status: Requested by sponsor,		✓
	or identified by PILOT Staff		
	Granted by Pilot Staff?		
D.	Has this device been the subject of a previous NSE decision?		✓
	If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E.	Has the sponsor been the subject of an integrity investigation?		✓
	If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Administrative Reviewer Signature: _____

Date: 11/17/94

Renita Y. Hoarel

Supervisory Signature: _____

Date: _____

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PILOT Evaluation Staff Screening Checklist
for Premarket Notifications (510(k)s)

Device Name: <i>Super Adigrip Denture Adhesive</i> ^{<i>Cream</i>}		K#: <i>K945402</i>	
Submitter Name: <i>Block Drug Co., Inc.</i>			
Items to Include in the 510(k)	✓ if needed		✓ if needed, & MISSING
	Yes	No	
1. General information: a) trade name, b) common name, c) establishment registration # d) address of manufacturing sites, e) device class, f) panel, g) new device or modification, h) predicate device(s) identified, i) submitter's name and address	✓	[shaded]	-
2. SHDA requirements: 510(k) summary or statement (any Class device)	✓	[shaded]	
Class III Certification & Summary (if Class III)			
3. Proposed labeling: a) device and package labels, b) package insert, c) statement of intended use, d) advertisements or promotional materials	✓	[shaded]	
Description of device (or modification) including diagrams, engineering drawings, or photographs, and service manuals	✓	[shaded]	
Comparison Information (similarities and differences) to named legally marketed equivalent device(s) (comparison table of attributes recommended) should include: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness	✓	[shaded]	
6. Biocompatibility data for all direct or indirect patient or user-contacting materials per Tripartite or ISO, OR, certification of identical material/formulation and method of sterilization to predicate			
7. Sterilization and expiration dating information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) validation method			
8. Software validation & verification per FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification			
9. Additional data and information per device specific OGRD/PILOT Staff guidance			
10. Kit information			

Items with shaded "No" and checked "Yes" are necessary for ALL submissions. Specific listed criteria in each item that are missing may be highlighted. Any checks in the last (Needed & MISSING) column requires a resubmission.

needed
 refuse to accept

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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

November 14, 1994

BLOCK DRUG CO., INC.
2149 HARBOR AVENUE
MEMPHIS, TN 38113
ATTN: FILOMENA KING

510(k) Number: K945462
Received: 07-NOV-94
Product: SUPER POLI-GRIP
DENTURE ADHESIVE
CREAM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), 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. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
 - 510(k) Status Coordinator
 - Division of Small Manufacturers Assistance (DSMA) (HFZ-2)
 - Center for Devices and Radiological Health, FDA
 - 5600 Fishers Lane
 - Rockville, Maryland 20857 USA
- Because of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

- (3) 510(k) information, including product name, 510(k) number date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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 Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

14

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

___ fax
___ mail

A. Sponsor Information:

- 1. Name of 510(k) sponsor:
2. Sponsor's mailing address:

B. Requester information:

- 1. Request name:
2. Requester affiliation with sponsor:
3. Requester mailing address:
4. Request fax number (if applicable):
5. Requester telephone number:

C. 510(k) information:

- 1. Product name:
2. 510(k) number:
3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE):

Name of contact person identified on firm's 510(k) submission:

I certify that the above information is accurate and truthful to the best of my knowledge.

(kev:2) Requester signature

Handwritten signature



ACKNOWLEDGEMENT COPY

BLOCK DRUG COMPANY, INC.

257 Cornelison Avenue Jersey City, N.J. 07302-3198
Telephone (201) 434-3000

November 1, 1994

Food and Drug Administration
Center for Devices and
Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED
7 NOV 94 14 47
FDA/CDRH/ODE/DNC

Re: 510(k) Notification

Gentlemen:

Enclosed herewith, is a premarket notification (510(k)) for the product "Super Poli-Grip® Denture Adhesive Cream" . This notification is submitted in accord with 21CFR 807.81.

The intent to market this device is considered confidential commercial information and therefore, this is a request that the indicated submittal sections be considered as such by FDA. The intent to market these devices, except for disclosures made to our employees and paid consultants, and to our law firms and advertising agencies as a matter of necessity, has not been disclosed.

A review of the device has been conducted against the FDA criteria for substantial equivalence. The device on behalf of which this 510(k) is submitted, "Super Poli-Grip® Denture Adhesive Cream" , has the same intended use, descriptive/performance information and technological characteristics of a currently marketed device and a device for which a 510(k) currently exists. Accordingly, it is respectfully requested that this device be considered "substantially equivalent" to the predecessor products outlined in this submission.

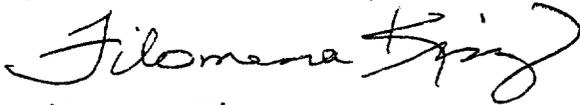
16

page 2

Food and Drug Administration
November 1, 1994

The earliest attention to this 510(k) submission would be greatly appreciated. Please contact the undersigned with all correspondence regarding this submission. Should there be questions regarding this submission, I can be reached at (800) 365-6500 or (201) 434-3000, both at extension 1794.

Sincerely,
BLOCK DRUG COMPANY, INC.



Filomena King
Regulatory Affairs Specialist

Enclosure: 510(k), In Duplicate
Cover Letter, In Triplicate





BLOCK DRUG COMPANY, INC.

257 Cornelison Avenue Jersey City, N.J. 07302-3198
Telephone (201) 434-3000

November 1, 1994

Food and Drug Administration
Center for Devices and
Radiological Health (HFZ-401)
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Rockville, MD 20850

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NOV 14 1994
FDA/CDRH/ODE/DHO

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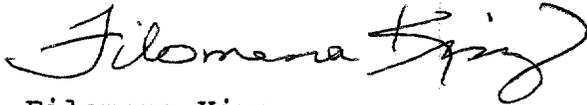
18

page 2

Food and Drug Administration
November 1, 1994

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BLOCK DRUG COMPANY, INC.



Filomena King
Regulatory Affairs Specialist

Enclosure: 510(k), In Duplicate
Cover Letter, In Triplicate

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Premarket Notification
510(k)

"Super Poli-Grip® Denture Adhesive Cream"

200001

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0002

510(k) ELEMENT CHECKLIST

Yes Present Omission Justified
 No Inadequate Omitted

I. Critical Elements:		
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Is device subject to review by CDRH?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>

0003

510(k) ELEMENT CHECKLIST - (con't)

Yes Present
Omission Justified

No Inadequate
Omitted

Page

<p>F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p>			12
<p>1. Device trade or proprietary name</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8
<p>2. Device common or usual name or classification name</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9
<p>3. Establishment registration number (only applies if establishment is registered)</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10
<p>4. Class into which the device is classified under (21 CFR Parts 862 to 892)</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<p>5. Classification Panel</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<p>6. Action taken to comply with Section 514 of the Act</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<p>7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12-14

0004 23

510(k) ELEMENT CHECKLIST - (con't)

Yes Present Omission Justified
 No Inadequate Omitted

Page

<p>8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request</p>	<p><input checked="" type="checkbox"/></p>	<p><input type="checkbox"/></p>	<p>246-252</p>
<p>9. For class III devices only, a class III certification and a class III summary</p>	<p><input type="checkbox"/> N/A</p>	<p><input type="checkbox"/></p>	
<p>10. Photographs of the device</p>	<p><input type="checkbox"/> N/A</p>	<p><input type="checkbox"/></p>	
<p>11. Engineering drawings for the device with dimensions and tolerances</p>	<p><input type="checkbox"/> N/A</p>	<p><input type="checkbox"/></p>	
<p>12. The marketed device(s) to which equivalence is claimed including labeling and description of the device</p>	<p><input checked="" type="checkbox"/></p>	<p><input type="checkbox"/></p>	<p>31-33</p>
<p>13. Statement of similarities and/or differences with marketed device(s)</p>	<p><input checked="" type="checkbox"/></p>	<p><input type="checkbox"/></p>	<p>16-17</p>
<p>14. Data to show consequences and effects of a modified device(s)</p>	<p><input type="checkbox"/> N/A</p>	<p><input type="checkbox"/></p>	<p>18-25</p>
<p>II. Additional Information that is necessary under 21 CFR 807.87(h):</p>	<p></p>	<p></p>	
<p>A. Submitter's name and address</p>	<p><input checked="" type="checkbox"/></p>	<p><input type="checkbox"/></p>	<p>246</p>

0005

24

Yes Present Omission Justified
 No Inadequate Omitted

Page

B. Contact person, telephone number and fax number	<input checked="" type="checkbox"/>	<input type="checkbox"/>	246
C. Representative/Consultant if applicable	<input type="checkbox"/>	N/A	
D. Table of Contents with pagination	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9
III. Additional Information that may be necessary under 21 CFR 807.87(h):			
A. Comparison table of the new device to the marketed device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	17
B. Action taken to comply with voluntary standards	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
C. Performance data marketed device			
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	21-22
animal testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	18-20
clinical data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	23-25

510(k) ELEMENT CHECKLIST - (con't)

Yes Present Omission Justified
 No Inadequate Omitted

Page

new device			
bench testing	<input checked="" type="checkbox"/>		21-22
animal testing	<input checked="" type="checkbox"/>		18-20
clinical data	<input checked="" type="checkbox"/>		23-25
D. Sterilization information	<input type="checkbox"/>	N/A	
E. Software information	<input type="checkbox"/>	N/A	
F. Hardware information	<input type="checkbox"/>	N/A	
G. If this 510(k) is for a kit, has the kit certification statement been provided?	<input type="checkbox"/>	N/A	
H. Is this device subject to issues that have been addressed in specific guidance document(s)? If yes, continue review with checklist from any appropriate guidance documents. If no, is 510(k) sufficiently complete to allow substantive review?	<input type="checkbox"/>		<input checked="" type="checkbox"/>
I. Other (specify)	<input type="checkbox"/>	N/A	<input type="checkbox"/>

Handwritten signature/initials

0007

(a) Device Name

- (1) Trade/Proprietary Name: "Super Poli-Grip® Denture Adhesive Cream"
- (2) The Common or Usual Name: Denture Adhesive
- (3) Classification Name: Adhesive, Denture Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt

0008



(b) Establishment Registration

The device establishment registration number of the Block Drug Company, Inc. facility in which this device will be manufactured is 1020379, located at:

2149 Harbor Ave.
Memphis, Tennessee 39113

or number 2650037 for the Block Drug Company, Inc. subsidiary:

Dentco Inc.
Rural Route 3
Humacao, Puerto Rico 00791

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0009

(c) Classification of Device

FDA has classified Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt in Class I. Final order was published in the Federal Register of August 12, 1987. The device was reviewed by the Dental Device Classification Panel.

The polyvinylmethylether maleic copolymer used in the manufacture of the proposed product undergoes a chemical reaction in the presence of excess water, strong base and at high temperature, whereby no maleic anhydride rings remain intact on the resin. The linear polymeric structure remains the same for the different salts of different substitutions. Therefore, substantial equivalence to the Class I device is being claimed for the proposed product. The identification contained in 21CFR 872.3490 follows.

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive

- (a) *Identification.* A carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

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0010

(d) Performance Standards

Performance standards for this type of denture adhesive have not been established.

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0011

(e) Proposed Labels, Labeling, Advertisements

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0012

PROPOSED SUPER POLI-GRIP® CARTON LABEL

SUPER POLI-GRIP®

ORIGINAL FRESH FLAVOR

...helps you enjoy more of your favorite foods!



Get the extra hold you need to help you eat more of your favorite foods.

SUPER POLI-GRIP denture adhesive:

- Helps hold dentures tight hour after hour.
- Forms a seal to help keep food from getting stuck between your dentures and gums.

Denture adhesives like **SUPER POLI-GRIP** can help alleviate gum irritation when used consistently as part of an effective oral care regimen.

So enjoy more of your favorite foods with **SUPER POLI-GRIP!** Available in cream and powder.

DENICO, Inc.
Humacao, P.R. 00791
Made in U.S.A.

SUPER POLI-GRIP®

SUPER Strong, Long Hold

POLI-GRIP®

NEW IMPROVED FORMULA

DENTURE ADHESIVE CREAM

Net wt 2.4 oz (68g)

SUPER Strong, Long Hold

POLI-GRIP®

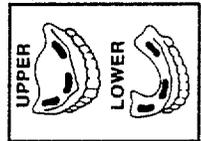
NEW IMPROVED FORMULA

Net wt 2.4 oz (68g)

DENTURE ADHESIVE CREAM

DIRECTIONS

1. Clean dentures thoroughly, using an effective cleanser. Try **DENTU-CREME**, **DENTU-GEL** or **POLIDENT** denture cleansers for best cleaning results.
2. Apply **SUPER POLI-GRIP** to clean dentures. Squeeze tube from the bottom up. **Keep cap and nozzle dry so that opening does not clog.**
3. Squeeze 3 short strips (1/4" to 1/2") onto each denture



as shown in diagram, not too close to denture edges. Adjust length of strips to individual needs.

4. Press dentures in place and hold firmly for a few moments.

EXTRA HOLDING POWER HINT

Rinse mouth before inserting dentures. **SUPER POLI-GRIP** reacts with moisture to form a tight seal to provide a firm hold.

Note: ill-fitting dentures may impair health. Consult your dentist regularly.

SUPER POLI-GRIP®

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0013

PROPOSED SUPER POLI-GRIP® TUBE LABEL

SUPER Strong, Long Hold
POLI-GRIP

DENTURE ADHESIVE CREAM

® Net wt
2.4 oz (68g)

Lot Code: XXXXX

SUPER
POLI-GRIP

*...helps you enjoy
more of your
favorite foods!*

Made in U.S.A.

DIRECTIONS

1. Clean dentures thoroughly.
 2. Apply SUPER POLI-GRIP to dentures.
Squeeze tube from the bottom up. Flatten, do not roll.
Keep cap and nozzle dry so that opening does not clog.
 3. Squeeze 3 short strips (1/4" to 1/2") onto each denture as shown in the diagram, not too close to denture edges. Adjust length of strips to individual needs.
 4. Press dentures in place and hold firmly for a few moments.
- Note: Ill-fitting dentures may impair health. Consult your dentist regularly



DENTCO, Inc. Humacao, P.R. 00791

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0014

(f) Substantial Equivalence Information

A review of the device has been conducted against the FDA criteria for substantial equivalence. The device on behalf of which this 510(k) is submitted, proposed Super Poli-Grip® Denture Adhesive Cream, has the same intended use, descriptive/performance information and general technological characteristics of devices for which the FDA has reviewed and granted a substantial equivalence letter or that are currently offered for sale.

The proposed Super Poli-Grip® Denture Adhesive Cream is substantially equivalent to two denture adhesives.

The proposed Super Poli-Grip® Denture Adhesive Cream is substantially equivalent to the Super Poli-Grip® product for which a letter of substantial equivalence was granted on August 29, 1986. The labeling for this product is duplicated in Attachment 1. The FDA substantial equivalence letter for the product with a number of K862876, is duplicated in Attachment 2.

The proposed Super Poli-Grip® product is also substantially equivalent to a device currently marketed under the brand name, Fixodent®. The "Fixodent®" Denture Adhesive product is currently in commercial distribution and is available in two flavors, regular and "Fresh". These two product versions differ only in flavor. Labeling for the Fixodent® products is included in Attachment 1. Fixodent® is marketed by the Procter and Gamble Company.

Evaluation of adhesion ability of the proposed Super Poli-Grip product versus Poli-Grip® 510(k) #K862876 has been conducted. Also, the efficacy of the proposed Super Poli-Grip® Denture Adhesive Cream versus Fixodent® Denture Adhesive has been evaluated. Animal studies have been performed with all three adhesives as well. A summary of these studies is included in section "(h) Safety and Efficacy Information". The safety and efficacy study information is submitted as substantiation of the judgement that the proposed Super Poli-Grip® product is substantially equivalent to both the 510(k) #K862876 Poli-Grip® and Fixodent® Denture Adhesives.

Table 1 shows equivalence of various attributes of the proposed and predicate Super Poli-Grip® and Fixodent® products. All products are intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort. All products contain carboxymethylcellulose sodium and salts of polyvinylmethylether maleic acid which serve as adhesives. All products consist largely of hydrocarbon vehicle bases composed of mineral oil and petrolatum. Product use indications, directions and sell claims made for the products are also similar.

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0015

(f) Substantial Equivalence Information cont.

TABLE 1

COMPARISON OF CHARACTERISTICS OF SELECTED DENTURE ADHESIVES

PRODUCT	FORM	INDICATION	ADHESIVE SYSTEM
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM (proposed)	Cream	Applied to denture prior to insertion, to improve denture retention and comfort	Carboxymethylcellulose sodium/ polyvinyl-methylether maleic acid salt
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM (#K862876)	Cream	Applied to denture prior to insertion, to improve denture retention and comfort	Carboxymethylcellulose sodium/ polyvinyl-methylether maleic acid salt
FIXODENT® DENTURE ADHESIVE CREAM	Cream	Applied to denture prior to insertion, to improve denture retention and comfort	Carboxymethylcellulose sodium/ polyvinyl-methylether maleic acid salt

See Attachments 3 and 4 for the formula and finished product specifications for the proposed Super Poli-Grip® Denture Adhesive Cream.

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(f) Substantial Equivalence Information cont.

TABLE 2

FORMULA (%) COMPARISON OF SELECTED DENTURE ADHESIVES

MATERIAL	SUPER POLI-GRIP® DENTURE ADHESIVE (proposed, ±15%)	SUPER POLI-GRIP® DENTURE ADHESIVE CREAM (#K862876)	FIXODENT®* DENTURE ADHESIVE CREAM
Carboxymethyl- cellulose sodium	24.00	24.00	20.21
Polyvinylmethyl- ether maleic acid			
(b)(4) (b)(4)	(b)(4)	(b)(4)	(b)(4)
Hydrocarbon vehicle base	45.00	45.89	46.34
(b)(4) (b)(4)	(b)(4)	(b)(4)	---
(b)(4) (b)(4)	---	(b)(4)	---
(b)(4) (b)(4)	(b)(4)	---	(b)(4)
Flavorant	0 - 0.40	---	---
Colorants	0 - 0.05	0.06	<0.1

*- Average of 3 lots.

Lot codes: 3026VK07, 3141VK and 3074VK

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0017

(g) Safety and Efficacy Information

In our judgement, the minor formula differences between the proposed Super Poli-Grip® Denture Adhesive Cream, the original Super Poli-Grip® and Fixodent® do not constitute "a significant change or modification that could significantly affect the safety or effectiveness of the device", nor is the device "to be marketed for a new or different indication for use". The following safety and efficacy evaluations are submitted as substantiation of this judgement.

Safety

The proposed Super Poli-Grip® Denture Adhesive Cream contains (b)(4) (b)(4) (methylvinylether maleic acid) partially substituted with sodium, zinc and magnesium cations to form (b)(4) (b)(4) mixed, partial salt. This salt is blended with carboxymethylcellulose (CMC) in a mineral oil and petrolatum base.

Salts of methylvinylether maleic acid (b)(4) (b)(4) are considered acceptable for use in commercially available denture adhesives (21 CFR, Parts 872.3490). Mineral oil and petrolatum are permitted for direct addition to food for human consumption (21 CFR, Parts 172.878 and 172.880). CMC is generally recognized as safe (GRAS, 21 CFR, Part 182.1745).

The active ingredients included in the proposed Super Poli-Grip® and Fixodent® products are essentially equivalent. Both contain a similar level of CMC. Both products also contain similar levels of methylvinylether maleic acid salt with Super Poli-Grip® containing (b)(4) (b)(4) and Fixodent® containing a (b)(4) (b)(4). This minor variation in the salts imposes no significant effect on product safety.

Magnesium is the second most plentiful cation of the intracellular fluids. The majority of magnesium is intracellular in the bone and muscle. It is an essential nutrient whose deficiency causes neuromuscular irritability, calcification and cardiac and renal damage, which can be prevented by supplementation. Magnesium is excreted principally by the kidney. Magnesium toxicity from excessive ingestion of magnesium salts is rare due to poor absorption from the intestine. Therefore, the presence of magnesium in the proposed product poses no additional safety concerns.

Like magnesium, zinc is an essential trace mineral in man. It is required by a vast number of metallo-enzymes for their proper functions in major metabolic pathways, most importantly, in respiration, carbohydrate and protein metabolism, as well as cell differentiation and replication. The kidney filters 2 g of zinc each day and the body content of zinc is modulated by homeostatic mechanisms with no accumulation upon continued exposure.

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0018

(g) Safety and Efficacy Information cont.

(b) (4)

(b)(4)

(b)(4) in the proposed product, as it is in Fixodent®, poses no additional safety concerns.

The acute safety profile of the proposed Super Poli-Grip® as well as the low toxicity potential of its ingredients support the overall safety of this product. Therefore, the safety profile of proposed Super Poli-Grip® Denture Adhesive Cream is considered comparable to that of the currently marketed Fixodent®.

The safety of the proposed Super Poli-Grip® Denture Adhesive Cream is also based on animal safety studies. The proposed Super Poli-Grip® Denture Adhesive Cream has demonstrated a satisfactory animal safety profile.

A summary of the acute oral toxicity, primary eye irritation and oral mucosal irritation studies conducted on the proposed Super Poli-Grip® Denture Adhesive Cream, Poli-Grip® 510(k) #K862876 and Fixodent® follows; full reports are presented in Attachments 5, 6 and 7.

Acute Oral Toxicity (Attachment 5)

Five male and five female Sprague-Dawley rats were employed for this study. After an acclimation period of five days, all animals were fasted overnight and subsequently dosed orally by gavage at a dose level of 5 g/kg body weight. The animals were observed for pharmacotoxic signs and mortality during a 15 day observation period. All animals were subjected to a gross necropsy examination at study termination.

All animals survived the study. Primary pharmacotoxic signs noted during study days 1-3 were loose stools (all test articles) and rales (Fixodent®). No product related abnormalities were noted in any of the animals at terminal necropsy. The oral LD₅₀ was greater than 5 grams per kilogram for all test articles.

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(g) Safety and Efficacy Information cont.

Primary Eye Irritation (Attachment 6)

The potential primary eye irritation of the product was evaluated using six New Zealand White rabbits. The right eyes of three rabbits were treated with the test substance and remained unrinsed. The remaining three rabbits were treated with the test substance and then irrigated with 20 ml of lukewarm tap water approximately four seconds after test article instillation. The untreated contralateral eye of each rabbit served as a control. Treated and untreated eyes were examined and ocular irritation was scored according to the Draize method at 24, 48 and 72 hours after test article instillation. Under these test conditions, maximum irritation scores for both rinsed and unrinsed eyes are as follows:

SCORING VALUES*

<u>PRODUCT</u>	<u>RINSED</u>	<u>UNRINSED</u>
PROPOSED SUPER POLI-GRIP®	1.3/110	2.0/110
SUPER POLI-GRIP® 510(k) #K862876	0.7/110	0.7/110
FIXODENT (Fresh)	1.3/110	1.3/110

*-See Attachment 6 for grading/scoring key

Under conditions of this study, the proposed Super Poli-Grip® product is classified as minimally irritating to the unrinsed and rinsed eye of the rabbit. The Poli-Grip 510(k) #K862876 and Fixodent® products are classified as practically non-irritating.

Oral Mucosal Irritation (Attachment 7)

One group of five male Sprague-Dawley rats was administered the product by four applications to the oral mucosa each day for four days. Prior to each application, the test sites were examined and scored. Following cessation of treatment the rats were examined and scored once daily for three days.

There was no irritation to the oral mucosa observed in any of the five animals treated during the course of the study. The mean oral irritation score was 0/6.0. Under the conditions of this study, all three test articles are considered to be non-irritating to the oral mucosa.

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0020

(g) Safety and Efficacy Information cont.

Efficacy

The efficacy of the proposed Super Poli-Grip® Denture Adhesive Cream, as for any other denture adhesive product, is based upon the products ability to improve denture retention and comfort. Testing has been conducted to evaluate the proposed product's efficacy versus both Super Poli-Grip 510(k) #K862876 and the currently marketed Fixodent® product.

The substantial equivalence in adhesion characteristics of the proposed Super Poli-Grip® Denture Adhesive Cream versus the 510(k) #K862876 product has been evaluated. Test methodology employed by Block Drug Company to evaluate and compare adhesion characteristics of denture adhesive products includes a test to determine Shear Strength of the product. While this method is used as a product development tool, it is indicative of adhesive efficacy.

Shear Strength is determined by measuring the force needed to separate acrylic plates which have been treated with test adhesive. Shear Strength data provides information relative to the initial stages of hydration of the adhesive. More simply, Shear forces are an indication of the ability of the adhesive to provide good denture retention in that Shear force is one component of denture dislodgement. The substrate employed in this test, acrylic, is a widely used denture base resin. The Dentists' Desk Reference: Materials, Instruments and Equipment, a publication by the American Dental Association, states that "acrylic resins represented such significant improvements in the construction of denture bases that by 1946 it was estimated that more than 95 percent of all dentures were constructed of methyl methacrylate polymer or copolymers...". Additionally, approximately 45% of all artificial teeth sold in the United States are made from plastic with most being based on acrylic resins. Therefore, results obtained from this test are representative of that which would be obtained from use on actual dentures.

The following Table (3) lists the results of Shear Strength testing that was conducted on the proposed Super Poli-Grip® versus the 510(k) #K862876 formula. It is apparent that a greater force is required to separate the plates treated with the proposed denture adhesive. This test indicates that at the very least, the products evaluated have substantially equivalent adhesion characteristics.

40

0021

(g) Safety and Efficacy Information cont.

TABLE 3

PRODUCT	SHEAR TEST (g/in ²)
Super Poli-Grip® 510(k) #K862876	(b)(4)
Proposed Super Poli-Grip®	(b)(4)

The substantial equivalence in efficacy of the proposed product to that of the currently marketed Fixodent® product has also been evaluated. Consumers were provided with blinded product samples, label use directions and a questionnaire. The consumers were asked to use each of the adhesives and to complete and return the questionnaire which included various product performance related questions. Since the study was consumer research oriented, results summarized (Table 4) include only those aspects of denture adhesive characteristics which are pertinent to the evaluation of efficacy and substantial equivalence. Results listed below were obtained from 79 respondents, all regular Fixodent® Denture Adhesive users.

TABLE 4

RESPONDENTS PREFERENCE (%)

PRODUCT CHARACTERISTIC	PROPOSED SUPER POLI-GRIP®	FIXODENT®	NO DIFFERENCE	NO ANSWER
QUICK HOLD	39.2*	22.8	34.2	3.8
LONG HOLD	46.8*	29.1	21.5	2.5
STRONG HOLD	48.1*	30.4	20.3	1.3
EASE OF REMOVAL- DENTURES	29.1	40.5	29.1	1.3
EASE OF REMOVAL-MOUTH	30.4	36.7	32.9	0
COMFORT	30.4	17.7	51.9	0

*-Significant difference at the 95% confidence level

41

0022

(g) Safety and Efficacy Information cont.

The results of this consumer test indicate that product performance for the proposed Super Poli-Grip® product is at least equivalent to that of Fixodent®, even among Fixodent® users. The proposed product demonstrates equivalent to superior performance versus Fixodent® for both denture retention and comfort.

Additional testing has been conducted to demonstrate equivalence in efficacy of the proposed adhesive to that of Fixodent®. A clinical study was conducted to demonstrate substantial equivalence between the proposed product and Fixodent® in their abilities to provide a significant improvement in the biting and chewing abilities of edentulous patients as demonstrated by bite force measurements.

The literature on the use of measuring devices to determine bite forces is extensive and involves various systems. These include simple levers, springs, manometers, steel ball impressions, pressure gauges and sylvon bellows. The electronic strain gauge technique, which was used in this study, was first introduced in 1948 by Howell and Manly. In 1949 Howell and Brudevold used these devices to measure chewing forces while the patients were eating various foods. Finn Brudevold (1951) followed this by measuring the chewing forces of denture wearers. He found in this study that a loss of only 15 percent force occurred when dentures were tested. Yurkstas and Curby measured chewing forces by placing strain gauges in several teeth of a denture and measured the biting forces during chewing of various foods. They found that forces up to about six pounds were needed to chew rolls while less than one pound force was needed for most foods.

Thirty subjects started and completed this clinical study. All subjects were in good general health (without allergy to dental or cosmetic products), all were over 18 years of age, all were able to understand the plan and scope of the study and all signed consent forms. The subjects were all able to generate a bite force of no less than 8 pounds and no greater than 40 pounds with a test adhesive prior to dislodgement at the screening visit. All subjects had full upper dentures which had not been altered in any way and were free of preexisting oral irritations. The subjects had not had gingival surgery within the previous 6 months and none were pregnant or lactating. The population consisted of 9 males and 21 females with a mean age of 60 years, a mean Kapur score of 1/1 and a mean denture bearing tissue score of 6.0.

The demographic data represent a normal subject panel with a range of ages of patients similar to the edentulous population in the United States. Likewise, both the Kapur Indices and Denture Bearing Tissue Scores of this panel are normal to the population with maxillary dentures. Lastly, within the constraints of the

42
0023

(g) Safety and Efficacy Information cont.

selection criteria the subjects have a normal distribution of bite force values at baseline and the various time periods when testings were run.

The following is a brief summary of the test methodology employed in this study. Baseline dislodgement measurements were made and recorded at the beginning of the study. Following baseline measurements, one of the adhesives was applied to the denture by the investigator's assistant. Adhesive application was made in accord with product label directions. The dentures were then pressed firmly into place. After five minutes, the subjects were asked to swallow and then bite down on the bite transducer until their maxillary denture dislodged or they reached maximum bite force. Measurements were taken at this time and subsequently at 1, 8, and 12 hours. This entire procedure was replicated after at least one day of subject nonparticipation, with the alternate product.

No adverse reactions were reported by any of the 30 subjects enrolled in the study.

Of highly significant importance are the differences noted between the mean baseline bite force values and the bite force values as affected by the application (both materials) for each of the four time periods. When t-Tests were run on these differences, a "p" value of 0.0001 was obtained versus baseline at all test times verifying the significance of the result of this comparison. Without adhesives it is anticipated that there would be constant dislodgement of the denture(s) while eating and talking. The data obtained after application of adhesives strongly support the retention of the denture(s) at all times for both actions cited above.

Bite force values at even the 5 minute time period, are sufficient to retain dentures while chewing various foods. In addition this effect is efficacious for the entire time period tested (12 h). Finally, it should be noted that there were no dietary restrictions placed upon the subjects. The variations that may have occurred in the biting and chewing of different kinds of foods did not affect the data obtained.

Table 5 lists mean bite force measurements as well as results of statistical evaluation of the data at the various time intervals.

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0024

(g) Safety and Efficacy Information cont.

Bite Force Measurements For Proposed Super Poli-Grip®
and Fixodent® Denture Adhesives

TABLE 5

TIME INTERVAL PRODUCT	MEAN BITE FORCE (LBS)	STD. DEVIATION	ANOVA
BASELINE SUPER POLI-GRIP® FIXODENT®			
5 MINUTE SUPER POLI-GRIP® FIXODENT®			
1 HOUR SUPER POLI-GRIP® FIXODENT®			
8 HOURS SUPER POLI-GRIP® FIXODENT®			
12 HOURS SUPER POLI-GRIP® FIXODENT®			

The study shows that the application of the test materials significantly improved the bite force values for the subjects at all time intervals versus baseline. This is a desired benefit to the subject. The chewing and biting forces needed for mastication and cutting are greatly exceeded by the forces generated during this study for both test materials. No statistical nor clinical differences exist between the proposed Super Poli-Grip® and Fixodent® Denture Adhesives.

The acute safety profile of the proposed Super Poli-Grip® as well as the low toxicity potential of the products' ingredients support the overall safety of this product. Product efficacy has been determined through laboratory, consumer research and clinical studies. In all cases, the proposed product has demonstrated comparable or better safety and efficacy characteristics when compared with the predicate products. Therefore, it is highly apparent that the proposed product is substantially equivalent to the Super Poli-Grip® 510(k) #K862876 and Fixodent® Denture Adhesive products for both safety and efficacy characteristics.

44

0025

(h) 510(k) Summary

A 510(k) Summary is included in Attachment 9.

48
0026

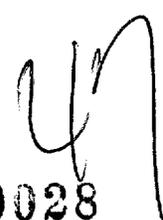
(i) Equivalence to Class III

Not applicable to the proposed Super Poli-Grip® Denture Adhesive Cream.

46
0027

(j) Statement of Full Disclosure

All data and information submitted in the premarket notification is truthful and accurate and to our knowledge, no material fact has been omitted.


0028

(k) Additional Information Statement

Attachment 8 includes a summary of the package stability study for the proposed Super Poli-Grip® Denture Adhesive Cream. The data collected indicates satisfactory stability with laminate tubes.

The information in Attachments 3, 4 and 8 is considered TRADE SECRET and CONFIDENTIAL.



0029

Attach.

|

49

ATTACHMENT 1

Labeling of Substantially Equivalent Products


0030

510(k) #K862876

SUPER POLI-GRIP DENTURE ADHESIVE CREAM

NEW FORMULA!
SUPER
POLI-GRIP



DIRECTIONS:

1. Clean dentures thoroughly. Super Poli-Grip can be used on either wet or dry dentures.
 2. Roll tube from bottom to top, warm in hand or warm water.
 3. Squeeze 3 short strips (1/4" to 1/2") onto each denture as shown in diagram, not too close to denture edges. Adjust length of strips according to individual need.
 4. Press dentures in place and hold firmly for a few moments.
- Note: Ill-fitting dentures may impair health. Consult your dentist regularly.

SUPER
POLI-GRIP
NEW FORMULA!

*
DENTICO, INC.
Jersey City, N.J. 07302.
Lumbago, P.O. 00661.
Toronto, Canada
Made in U.S.A.

NEW
FORMULA!

SUPER
POLI-GRIP
DENTURE ADHESIVE CREAM

NET WT 1.40 OZ. (39.7 g.)



NEW
FORMULA!

SUPER
POLI-GRIP
DENTURE ADHESIVE CREAM

NET WT 1.40 OZ. (39.7 g.)

NEW FORMULA!
SUPER
POLI-GRIP

NEW
FORMULA!

SUPER
POLI-GRIP
DENTURE ADHESIVE CREAM

NET WT 1.40 OZ. (39.7 g.)

PGS-45

0031

FIXODENT® CARTON LABEL

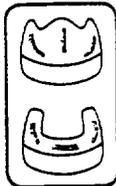
NEW, EASY TWIST CAP
ON 2.4 OZ. TUBE

GUARANTEED LONG, STRONG HOLD

Fixodent®

DENTURE ADHESIVE CREAM

NET WT. 2.4 OZ.



Directions: Clean dentures thoroughly. Apply FIXODENT to dentures by squeezing short strips as shown in the diagram. Press dentures firmly in place and hold briefly. It may take a few trials to see what amount of product is best for you. Do not apply too close

to denture edges. If oozing occurs, use a little less product. To avoid clogging, keep cap and nozzle dry. To help clean gums, use a soft toothbrush and warm water.

Note: Consult your dentist regularly to ensure proper fitting dentures.



EASY TWIST COMMENDED BY
ARTHRITIS FOUNDATION®

GUARANTEED LONG, STRONG HOLD

Fixodent

DENTURE ADHESIVE CREAM

NET WT. 2.4 OZ.

Fixodent

New Bigger EASY TWIST CAP Opens And Closes with One Quick Turn!

And The Nozzle is Designed To Reduce Clogging and Make Squeezing Easier!

Fixodent provides the same guaranteed strong holding power so you can laugh, talk, and eat with greater comfort and confidence. Fixodent's hold even stands up to the hottest liquids!

FIXODENT and forget it!

Made in U.S.A. by PROCTER & GAMBLE
Cincinnati, Ohio 45202.

SATISFACTION GUARANTEED OR YOUR MONEY BACK

If, for any reason, you are not satisfied with this product, please mail remaining product and reason for return for a full refund to: FIXODENT, P. O. Box 5552, Cincinnati, OH 45201-5552

G If you have any questions or comments, please call us toll free at 1-800-543-7270.

FIXODENT® TUBE LABEL

SAME GREAT HOLD-EASY TWIST CAP

Fixodent®

DENTURE ADHESIVE CREAM

SQUEEZE TUBE FROM THE BOTTOM UP. FLATTEN, DO NOT ROLL.

Directions: Clean dentures thoroughly. Apply FIXODENT to dentures by squeezing short strips as shown in the diagram. Press dentures firmly in place and hold briefly. It may take a few trials to see what amount of product is best for you. Do not apply too close to denture edges. If oozing occurs, use a little less product. To avoid clogging, keep cap and nozzle dry. To help clean gums, use a soft toothbrush and warm water.

Note: Consult your dentist regularly to ensure proper fitting dentures.

Made in U.S.A. by PROCTER & GAMBLE
Cincinnati, Ohio 45202. K 68762

G If you have any questions or comments, please call us toll free at 1-800-543-7270. NET WT. 2.4 OZ.

4652

SA

0032

FIXODENT® FRESH CARTON LABEL

STRONG HOLD, FRESH FEELING

Fixodent® Fresh

DENTURE ADHESIVE CREAM

NET WT 2.4 OZ (68 g)



Cools And Freshens Your Mouth - While It Provides Strong, Long Holding Power

Fixodent Fresh gives your mouth a cool, clean feeling without interfering with the taste of food. And the Fixodent name guarantees strong holding power so you can eat, talk, and enjoy the activities you like.

FIXODENT FRESH and forget it!

Made in U.S.A. by PROCTER & GAMBLE Cincinnati, Ohio 45202 U.S. Patent 5,073,604 © 1993 P&G

SATISFACTION GUARANTEED OR YOUR MONEY BACK

If, for any reason, you are not satisfied with this product, please mail remaining product and reason for return for a full refund to: FIXODENT, P.O. Box 5552, Cincinnati, OH 45201-5552

Questions? Comments? Call toll free at 1-800-543-7270.

NEW IMPROVED NOZZLE
SAME EASY TWIST CAP

STRONG HOLD, FRESH FEELING

Fixodent® Fresh

DENTURE ADHESIVE CREAM

NET WT 2.4 OZ (68 g)



DIRECTIONS

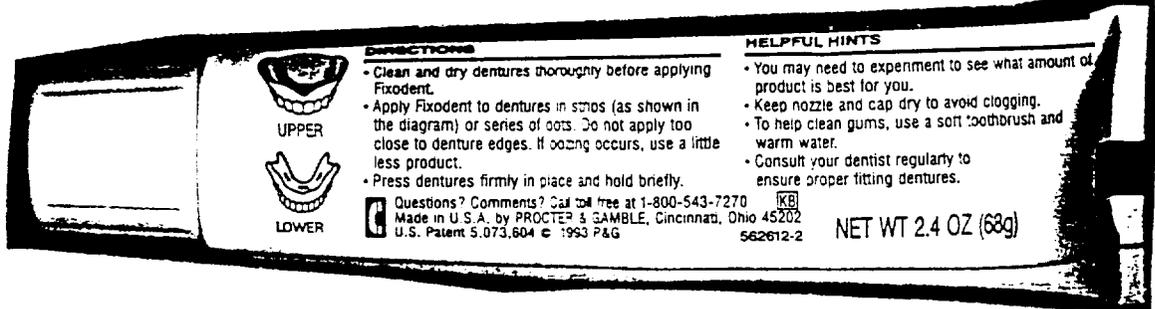
- Clean and dry dentures thoroughly before applying Fixodent.
- Apply Fixodent to dentures in strips (as shown in the diagram) or series of dots. Do not apply too close to denture edges. If oozing occurs, use a little less product.
- Press dentures firmly in place and hold briefly.

HELPFUL HINTS

- You may need to experiment to see what amount of product is best for you.
- Keep nozzle and cap dry to avoid clogging.
- To help clean gums, use a soft toothbrush and warm water.
- Consult your dentist regularly to ensure proper fitting dentures.



0 76660 00465 8



DIRECTIONS

- Clean and dry dentures thoroughly before applying Fixodent.
- Apply Fixodent to dentures in strips (as shown in the diagram) or series of dots. Do not apply too close to denture edges. If oozing occurs, use a little less product.
- Press dentures firmly in place and hold briefly.

Questions? Comments? Call toll free at 1-800-543-7270. Made in U.S.A. by PROCTER & GAMBLE, Cincinnati, Ohio 45202 U.S. Patent 5,073,604 © 1993 P&G

HELPFUL HINTS

- You may need to experiment to see what amount of product is best for you.
- Keep nozzle and cap dry to avoid clogging.
- To help clean gums, use a soft toothbrush and warm water.
- Consult your dentist regularly to ensure proper fitting dentures.

NET WT 2.4 OZ (68g)



0033

Attach.

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ATTACHMENT 2

Substantial Equivalence Letter for Super Poli-Grip® Denture
Adhesive- 510(k) #K862876



0034



Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUL 29 1986

Howard Feinman
Manager, Regulatory Affairs
Block Drug Company, Inc.
257 Cornelison Avenue
Jersey City, New Jersey 07302

Re: K862876
New Super Poli-Grip
Denture Adhesive Cream
Dated: July 25, 1986
Received: July 30, 1986

Dear Mr. Feinman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Pre-market Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HF7-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of OB-GYN, ENT,
and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

56 0035

Attach.

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ATTACHMENT 3

DEVICE FORMULA

58 0036

DEVICE FORMULA

PROPOSED SUPER POLI-GRIP® DENTURE ADHESIVE

COMPONENT	PERCENT BY WEIGHT (± 15%)
Carboxymethylcellulose sodium	24.00%
Polyvinylmethylether co-maleic acid salt (b)(4) (b)(4)	(b)(4) (b)(4)
Petrolatum	29.00%
Mineral Oil	16.00%
Flavorant	0 - .40%
(b)(4) (b)(4)	(b)(4) ⁴
(b)(4) (b)(4)	(b)(4) ⁴
Colorants: D&C Red 30 D&C Red 7	0 - .03% 0 - .02%

0037

Attach.

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ATTACHMENT 4

FINISHED PRODUCT SPECIFICATIONS

(Methods for testing against product specifications will be provided upon request)

Ud 0038

FINISHED PRODUCT SPECIFICATIONS

PROPOSED SUPER POLI-GRIP® DENTURE ADHESIVE

DESCRIPTION

Pinkish-red cream, free of lumps and particles, with a minty flavor.

PROPERTIES AND CONDITIONS	SPECIFICATION
Product Appearance	Pinkish-red cream, free of lumps and particles
(b)(4) (b)(4)	(b)(4)
Viscosity (RT)	(b)(4)
Polyvinylmethylether maleic acid salt	
Carboxymethylcellulose sodium	
Microbiology:	
Aerobic Plate Count	
Yeasts, Molds	
Pathogens*	

*- Pseudomonas species, Staphylococcus aureus, E. Coli and Salmonella species.

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ATTACHMENT 5
ACUTE ORAL TOXICITY

W 0040

ACUTE ORAL TOXICITY STUDY IN RATS

**PROPOSED SUPER POLI-GRIP■
DENTURE ADHESIVE CREAM**

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Pages 75 through 81 redacted for the following reasons:

Exemption (b)(4)

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APPENDIX II

PROTOCOL

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APPENDIX III

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Exemption (b)(4)

ACUTE ORAL TOXICITY STUDY IN RATS

**SUPER POLI-GRIP■
DENTURE ADHESIVE CREAM
510(k) #862876**

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APPENDIX II

PROTOCOL

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APPENDIX III

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Exemption (b)(4)

ACUTE ORAL TOXICITY STUDY IN RATS

**FIXODENT■
DENTURE ADHESIVE CREAM**

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APPENDIX II

PROTOCOL

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Exemption (b)(4)

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Exemption (b)(4)

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ATTACHMENT 6
PRIMARY EYE IRRITATION

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MD

PRIMARY EYE IRRITATION STUDY IN THE ALBINO RABBIT

**PROPOSED SUPER POLI-GRIP■
DENTURE ADHESIVE CREAM**

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APPENDIX II

PROTOCOL

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Exemption (b)(4)

APPENDIX III

RAW DATA

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Pages 151 through 157 redacted for the following reasons:

Exemption (b)(4)

PRIMARY EYE IRRITATION STUDY IN THE ALBINO RABBIT

**SUPER POLI-GRIP■
DENTURE ADHESIVE CREAM
510(k) #862876**

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Pages 159 through 167 redacted for the following reasons:

Exemption (b)(4)

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APPENDIX II

PROTOCOL

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Exemption (b)(4)

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APPENDIX III

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Exemption (b)(4)

PRIMARY EYE IRRITATION STUDY IN THE ALBINO RABBIT

**FIXODENT■
DENTURE ADHESIVE CREAM**

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Exemption (b)(4)

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APPENDIX II

PROTOCOL

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Exemption (b)(4)

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APPENDIX III

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Exemption (b)(4)

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ATTACHMENT 7

ORAL MUCOSAL IRRITATION

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ORAL MUCOSAL IRRITATION STUDY IN RATS-CTFA

**PROPOSED SUPER POLI-GRIP■
DENTURE ADHESIVE CREAM**

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Exemption (b)(4)

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APPENDIX II

PROTOCOL

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Exemption (b)(4)

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APPENDIX III

RAW DATA



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Pages 231 through 235 redacted for the following reasons:

Exemption (b)(4)

ORAL MUCOSAL IRRITATION STUDY IN RATS-CTFA

**SUPER POLI-GRIP■
DENTURE ADHESIVE CREAM
510(k) #862876**

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APPENDIX II

PROTOCOL

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Exemption (b)(4)

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APPENDIX III

RAW DATA



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Exemption (b)(4)

ORAL MUCOSAL IRRITATION STUDY IN RATS-CTFA

**FIXODENT■
DENTURE ADHESIVE CREAM**

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Pages 258 through 264 redacted for the following reasons:

Exemption (b)(4)

(b)(4)

APPENDIX II

PROTOCOL

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Exemption (b)(4)

APPENDIX III

RAW DATA

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Pages 273 through 277 redacted for the following reasons:

Exemption (b)(4)

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ATTACHMENT 8
PRODUCT STABILITY

270 0343

ATTACHMENT 8

Summary Table For Product Package Stability

STABILITY DATA PROPOSED SUPER POLI-GRIP® DENTURE ADHESIVE CREAM

PARAMETERS	STABILITY REQUIREMENT	TEST INTERVAL						
		0		1 mos		3 mos		
		RT	40°C	RT	40°C	RT	40°C	
Product Appearance	Pinkish-red cream, free of lumps and particles	CON-FORMS	CON-FORMS	CON-FORMS	CON-FORMS	CON-FORMS	CON-FORM	
pH (2% solution)	(b)(4)							
Viscosity (RT)								
Polyvinylmethylether maleic acid salt								
Carboxymethyl-cellulose sodium								
Non-Extractable Solids								(b)(4)
Hexane Soluble								
Microbiology:								
Aerobic Plate Count								
Yeasts, Molds								
Pathogens*								

*- Pseudomonas species, Staphylococcus aureus, E. Coli and Salmonella species.

AM 0344

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ATTACHMENT 9

510(k) Summary

SUPER POLI-GRIP DENTURE ADHESIVE CREAM

213 0245

510(k) Summary

SUPER POLI-GRIP DENTURE ADHESIVE CREAM

AM 0246

510(k) Summary
SUPER POLI-GRIP DENTURE ADHESIVE CREAM

- [1] Submitter's name: BLOCK DRUG COMPANY, INC.
 Address: 257 Cornelison Ave.
 Jersey City, NJ 07302-9988

 Telephone Number: (201) 434-3000 Ext. 1794
 Fax Number: (201) 332-2362

 Contact Person: Filomena King

 Date Prepared: November 1, 1994
- [2] Name of Device: Super Poli-Grip
 Common Name: Denture Adhesive
- [3] Identification of device to which substantial equivalence
 is claimed.

 Super Poli-Grip® Denture Adhesive Cream (#K862876)
 Block Drug Company, Inc.
 257 Cornelison Ave.
 Jersey City, NJ 07302

 Fixodent® Denture Adhesive Cream
 Procter & Gamble
 Cincinnati, Ohio 45202

MS
0247

510(k) Summary
SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

[4] Description of device that is the subject of the pre-market notification submission:

How the device functions:

Super Poli-Grip® is a cream product which is applied to the base of a denture before the denture is inserted in the mouth to improve denture retention and comfort.

Basic scientific concept that form the basis for the device:

The Poli-Grip® Denture Adhesive is a cream that derives retentive properties from carboxymethylcellulose and polyvinylmethylether maleic acid salt. These adhesives spread between the denture and tissue surface, excluding air. Retention is achieved through the increase in adhesion properties that develop when adhesive salts swell in the presence of saliva.

Significant physical characteristics:

Poli-Grip® Denture Adhesive Cream is a smooth, homogenous pinkish-red cream with a pleasant flavor.

Performance characteristics:

The Poli-Grip® Denture Adhesive Cream is specially formulated to form a tight seal and provide a firm hold of dentures. The improved denture retention afforded by the Poli-Grip® product enables the consumer to masticate all types of food with ease and comfort.

Device design and Device materials used:

The Poli-Grip® Denture Adhesive Cream is a ready to use product composed of adhesives, hydrocarbon vehicle base, preservative, flavorant and colorant.

Device physical properties:

Super Poli-Grip® Denture Adhesive Cream is a smooth, homogeneous cream with a characteristic flavor.

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[5] Intended use:

Super Poli-Grip® is a cream product which is applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

Patient population:

Patients which may require better retention and comfort of ill-fitting dentures.

Difference between Super Poli-Grip® and the substantially equivalent product:

Minor formula differences exist between the Super Poli-Grip® Denture Adhesive Cream and the substantially equivalent products. These differences do not detract from the ability of the product to perform as a denture adhesive, to aid in the retention and comfort of dentures.

Why the difference does not effect the safety and effectiveness of the device.

There are no critical differences between Super Poli-Grip® Denture Adhesive Cream and the substantially equivalent products. The oral toxicity, oral mucosal irritation and eye irritancy of the Super Poli-Grip® product have been determined. The Super Poli-Grip® product has demonstrated a satisfactory animal safety profile. Additionally, efficacy data indicates that the Super Poli-Grip product is highly efficacious with no significant difference in performance with a predicate Super Poli-Grip® and a currently marketed product.

[6] How they compare in technology, (design, material, chemical composition, or energy source) in [3]:

There is no significant difference between the products. While product formulae may vary somewhat, all provide good denture retention and comfort to the consumer.

[7] Safety and Efficacy Information

Safety

The safety of Super Poli-Grip® Denture Adhesive Cream has been determined through animal safety studies. The product has demonstrated a satisfactory animal safety profile.

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SUPER POLI-GRIP® DENTURE ADHESIVE CREAM cont.

A summary of the acute oral toxicity, eye irritation and oral mucosal irritation studies conducted on Super Poli-Grip® Denture Adhesive Cream follows.

Acute Oral Toxicity

Five male and five female Sprague-Dawley rats were employed for this study. After an acclimation period of five days, all animals were fasted overnight and subsequently dosed orally by gavage at a dose level of 5 g/kg body weight. The animals were observed for pharmacotoxic signs and mortality during a 15 day observation period. All animals were subjected to a gross necropsy examination at study termination.

All animals survived the study. No product related abnormalities were noted in any of the animals at terminal necropsy. The oral LD₅₀ was greater than 5 grams per kilogram.

Primary Eye Irritation Study

The potential primary eye irritation of the product was evaluated using six New Zealand White rabbits. The right eyes of three rabbits were treated with the test substance and remained unrinsed. The remaining three rabbits were treated with the test substance and then irrigated with 20 ml of lukewarm tap water approximately four seconds after test article instillation. The untreated contralateral eye of each rabbit served as a control. Treated and untreated eyes were examined and ocular irritation was scored according to the Draize method at 24, 48 and 72 hours after test article instillation.

The maximum mean primary eye irritation score in non-rinsed and rinsed eyes was found to be 2.0/110.0 and 1.3/110.0 respectively. Under conditions of this study, the product is classified as minimally irritating to the unrinsed and rinsed eye of the rabbit.

Oral Mucosal Irritation

One group of five male Sprague-Dawley rats was administered the product by four applications to the oral mucosa each day for four days. Prior to each application, the test sites were examined and scored. Following cessation of treatment the rats were examined and scored once daily for three days.

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There was no irritation to the oral mucosa observed in any of the five animals treated during the course of the study. The mean oral irritation score was 0/6.0. Under the conditions of this study, Super Poli-Grip® Denture Adhesive Cream is considered to be non-irritating to the oral mucosa.

Efficacy

The efficacy of Super Poli-Grip® Denture Adhesive Cream, as for any other denture adhesive product, is based upon the products ability to improve denture retention and comfort. Testing has been conducted to evaluate the proposed product's efficacy versus both Super Poli-Grip 510(k) #K862876 and the currently marketed Fixodent® product.

A Shear Strength study was conducted on the proposed Super Poli-Grip® versus the 510(k) #K862876 formula. It is apparent that a greater force is required to separate the plates treated with the proposed denture adhesive. Test results indicate that at the very least, the products evaluated have substantially equivalent adhesion characteristics.

The substantial equivalence in efficacy of the proposed product to that of the currently marketed Fixodent® product has also been evaluated. Consumers were provided with blinded product samples, label use directions and a questionnaire. The consumers (all regular Fixodent® users) were asked to use each of the adhesives and to complete and return the questionnaire which included various product performance related questions.

The results of this consumer test indicate that product performance for the proposed Super Poli-Grip® product is at least equivalent to that of Fixodent®, even among Fixodent® users. The proposed product demonstrates equivalent to superior performance versus Fixodent® for both denture retention and comfort.

Additional testing has been conducted to demonstrate equivalence in efficacy of the proposed adhesive to that of Fixodent®. A clinical study was conducted to demonstrate substantial equivalence between the proposed product and Fixodent® in their abilities to provide a significant improvement in the biting and chewing abilities of edentulous patients as demonstrated by bite force measurements and to examine adverse effects.

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The electronic strain gauge technique was used in this study. Study results show that the application of the test materials significantly improved the bite force values for the subjects at all times intervals versus baseline. This is a desired benefit to the subject. The chewing and biting forces needed for mastication and cutting are greatly exceeded by the forces generated during this study for both test materials. No statistical nor clinical differences exist between the proposed Super Poli-Grip® and Fixodent® Denture Adhesives.

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