



Food and Drug Administration
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Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. M. Th. Plaumann
Managing Board
VOCO GMBH
Anton-Flettner-Strasse 1-3
Cuxhaven Germany D-27472

OCT 21 2010

Re: K101104
Trade/Device Name: VOCO Paste
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: September 27, 2010
Received: September 29, 2010

Dear Mr. Plaumann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2- Mr. Plaumann

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 101104

Device Name: VOCO Paste

OCT 21 2010

Indications for Use:

VOCO Paste is intended to be used after professional tooth whitening, professional tooth cleaning and for prevention and control of hypersensitivities.

Prescription Use X

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101104

K101104 / A2

VOCO GmbH • Postfach 767 • 27457 Cuxhaven • Germany

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K-48

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info@voco.de
www.voco.de

Dr. TG/KFr 22/06/2010

Re.: Traditional 510 (k) submission for the preparation Remin Pro, K101104

Dear Mrs Browne,

Please find enclosed our statement to your email of 08.06.10 concerning the above mentioned Medical Device.

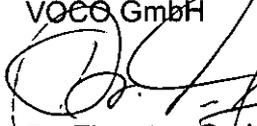
We have also added the revised Summary Report. Please pay attention to our application form page 3 where we have checked off "510 (k) statement". The enclosed Summary Report contains confidential information. Therefore we prefer to publish the 510 (k) statement in the FDA Registration Database.

In case of any questions or if you need additional documents, please feel free to contact the undersigning person by mail (t.gerkensmeier@voco.de) phone (+49-4721-719-200 or fax (+49-4721-719-219) for more information..

Many thanks for your help and cooperation,

with best regards
VOCO GmbH

VOCO GmbH
Anton-Flettner-Str. 1-3
27472 Cuxhaven


Dr. Thorsten Gerkensmeier
(Regulatory Affairs)



Enclosures

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Dr. TG/KFr

17/06/2010

Re.: Traditional 510 (k) submission for the preparation Remin Pro, K101104

Your email dated 08.06.2010 - Deficiencies

Dear Mrs. Browne,

Please find here our statements:

(b) (4)



(b) (4)



In case of any questions or if you need additional documents, please feel free to contact us by mail (t.gerkensmeier@voco.de) phone (+49-4721-719-200 or fax (+49-4721-719-219) for more information..

Many thanks for your help and cooperation,

with best regards
VOCO GmbH


Dr. Thorsten Gerkensmeier
(Regulatory Affairs)

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Germany



Enclosures

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Summary Report

510(k) SUMMARY
according to
21CFR807.92

a.1.

Applicant: VOCO GmbH, Anton-Flettner-Str. 1-3,
27472 Cuxhaven/Germany

Phone: +49 4721 719 0

Contact: M. Th. Plaumann

Date prepared: April 14, 2010

a.2.

Trade or proprietary name: **Remin Pro**

Classification name: Agent, Polishing, Abrasive, Oral Cavity (872.6030)

a.3.

Predicate device: GC MI Paste Plus, K070854

a.4.

Device description:

Remin Pro is a water-based cream that contains hydroxyl apatite and fluoride.

Remin Pro provides extra protection for teeth and, in doing so, it helps neutralize acids in acid-forming bacteria in plaque. **Remin Pro** additionally facilitates the neutralization of other acids in the mouth.

The application of **Remin Pro** is not recommended for patients under 6 years or for home use on children under 12 years.

a.5.

Intended use:

intended form

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

a.6.

Technological characteristics:

Remin Pro and the legally marketed device K070854 (**GC MI Paste Plus, GC America**) share the same indications but have different features. The components of **Remin Pro** serve the same purpose as the ingredients of the predicate device. The components of **Remin Pro** cover materials for the hypersensitivity prevention and control because it helps to neutralize acid challenges from cariogenic bacteria in plaque. The predicate device uses amorphous calciumphosphate and fluoride to protect enamel and seal dentinal tubules. This effect is achieved by the formation of local calciumfluoride – and subsequently fluoroapatite deposits which can also be generated by other sources like a generic fluoride containing tooth paste for home use.

In contrast to the predicate device **Remin Pro** does not contain amorphous calciumphosphate and fluoride but it contains finely dispersed apatite and additional fluoride which is capable of neutralizing acid challenges and strengthening of tooth hard tissues by creating similar deposits of calciumfluoride and apatite on the tooth surface.

The prior use of all of the components of **Remin Pro** in legally marketed devices and/or the known biological function of the ingredients support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

We believe that the prior use of the components of **Remin Pro** in legally marketed devices and the performance data and results provided support the safety and effectiveness of **Remin Pro** for the intended use.

Compositional similarity of Remin Pro and the predicate device GC MI Paste Plus

Both preparations serve the same purpose, thus, the components are functionally equivalent.
 The ingredients are chemically comparable as well featuring similar properties.

Function	Ingredient	Remin Pro	GC MI Paste Plus
Inert Filler	Pigments	(b) (4)	
Stabilizer	Parabene		
Matrix	Glycerine		
	Water		
	Propyleneglycol		
Thickener	Carboxymethylcellulose		
	Silica		
Remineralization Support	Phosphoric acid		
	CPP-ACP		
	Hydroxylapatite		
	Sodium Fluoride		
Additives	Sweetener		
	Flavors		

Remin Pro and the predicate device feature components which are intended to prevent the effects of the acidic challenge of human enamel and dentin.

The prior use of all of the components of **Remin Pro** in legally marketed devices support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

b.1.

Product performance data for Remin Pro and the predicate device GC MI Paste Plus:

The predicate device GC MI Paste is a paste which is intended to be applied to the teeth surfaces using suitable application aids. The most important material properties refer to the consistency and the pH value. While the consistency directly influences the applicability the pH value impacts the patient's acceptance and is important for the tooth hard tissues. pH values lower than 6 and higher than 8 will cause unpleasant sensations in many patients and may eventually damage the tooth hard tissues.

Both materials, Remin Pro and the predicate device are water based. They can be mixed and dissolved in water at any ratio.

(b) (4)



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b.2.

Clinical tests

Remin Pro is based on materials which are commonly used in dental materials and food and are generally accepted to be safe which is particularly true for the natural mineral apatite. Apatite is present in many biological tissues and can be naturally found in teeth and bone. Because of its excellent biocompatibility apatite is a component of different medical preparations e.g. bone cements.

The efficacy of Remin Pro is guaranteed by the fine apatite particles which dissolve more quickly than the apatite containing natural tooth surface. It is a commonly known physical process that due to higher surface area and surface energy smaller particles more easily dissolve in the presence of larger crystals of the same material. Small particles also physically attach to surfaces due to their surface energy and in this way serve as a mineral depot.

In case of an acidic environment Remin Pro protects the tooth from de-mineralization and sets free the minerals calcium and phosphate.

b.3.

Conclusions

Remin Pro is considered a very low risk preparation with beneficial effects to the tooth hard tissues. By neutralizing acids in the oral cavity and providing important minerals Remin Pro prevents physical damage to the tooth surfaces and quickly restores a healthy oral environment.

About SE

VOCO GmbH, June 14th, 2010


Manfred Thomas Plaumann
(Managing Board)

VOCO GmbH
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27472 Cuxhaven
Germany



[Caries Res.](#) 2009;43(1):57-63. Epub 2009 Feb 10.

Influence of fluoride availability of dentifrices on eroded enamel remineralization in situ.

[Hara AT](#), [Kelly SA](#), [González-Cabezas C](#), [Eckert GJ](#), [Barlow AP](#), [Mason SC](#), [Zero DT](#).

Oral Health Research Institute, Indiana University School of Dentistry, Indianapolis, IN 46202-2876, USA.

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Abstract

Remineralization of eroded enamel by dentifrices containing similar sources/concentrations of fluoride was investigated in situ. Fifty-three subjects completed a double-blind crossover study with 3 randomly assigned dentifrice treatments: placebo (0 ppm F, PD); reference (1,450 ppm NaF, RD) and test (1,450 ppm NaF + 5% KNO₃, TD). Fluoride availability for each dentifrice was analyzed in vitro by standard tests (1-min fluoride release rate and enamel fluoride uptake). The subjects wore palatal appliances holding bovine enamel specimens previously eroded in vitro. Surface microhardness was determined before and after the in vitro erosive challenge, after in situ remineralization and after a second in vitro erosive challenge. ANOVA and pairwise comparisons were performed ($\alpha=0.05$). TD was superior to RD in the fluoride release tests, but similar to RD in the enamel fluoride uptake test. The mean percent surface microhardness recovery was 21.9 (standard deviation 8.0) for PD, 28.6 (8.0) for RD and 36.0 (8.0) for TD. The mean percent relative erosion resistance change was -58.8 (12.7) for PD, -31.3 (12.7) for RD and -27.3 (12.6) for TD. Both fluoride-containing dentifrices provided superior remineralization ($p<0.001$) and erosion resistance ($p<0.001$) compared to PD. The percent surface microhardness recovery demonstrated by the TD was significantly greater than for the RD ($p<0.001$). There was no significant difference ($p=0.073$) between TD and RD in relative resistance to further erosive challenge. The results suggest that fluoride availability may be different in dentifrices with similar sources/concentrations of fluoride, providing different levels of remineralization of eroded enamel. Copyright 2009 S. Karger AG, Basel.

PMID: 19204389 [PubMed - indexed for MEDLINE]



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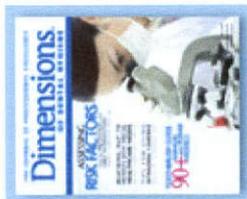
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The Dynamic Process of Demineralization and Remineralization



The remineralization of incipient carious lesions as an alternative to conventional caries treatment.

By Michael W. Roberts, DDS, MScD, and J. Timothy Wright, DDS, MS

Dental caries is a complex, multifactorial, transmittable infectious disease caused by the process of demineralization and remineralization in the presence of fermentable dietary carbohydrates, saliva, and cariogenic oral flora. The disease continues to be highly prevalent in the United States and other countries around the world. The 2001 Report of the Surgeon General—*Oral Health in America*—stated that 7% of children aged 2 years to 17 years had unmet dental needs.¹ A 2006 survey found that 50% of children aged 5 years to 9 years had at least one cavity or filling with this proportion increasing to 78% among 17-year-olds.²

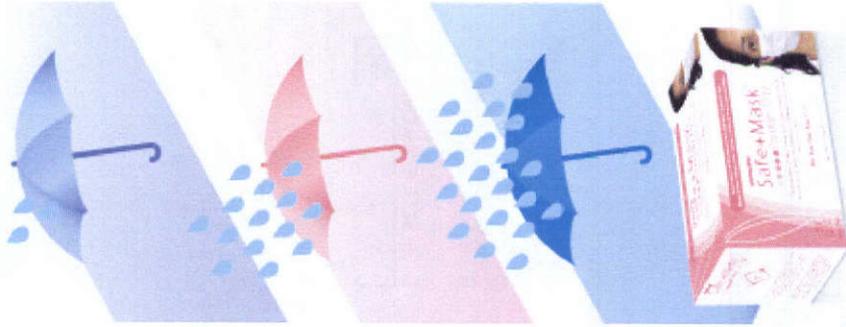
Shortly after the teeth erupt into the mouth, a protective layer of saliva-derived proteins—the acquired enamel pellicle (AEP)—forms on the tooth. A sticky, tenacious, and highly complex biofilm is created when dental plaque forms on the AEP and oral flora colonize it. The process of demineralization and dental caries formation begins when cariogenic microorganisms are present in large numbers and dietary fermentable carbohydrates become available in the dental biofilm.³ A white spot lesion initially appears. If demineralization continues, it results in cavitation of the tooth.

Many oral microorganisms are capable of forming organic acids that reduce the pH of the dental plaque when exposed to carbohydrates. Numerous streptococcus strains, including *S. mutans*, *S. sanguinis*, and to a lesser extent, *Lactobacillus*, are considered important bacteria involved in the development of dental caries. However, our knowledge of the initial colonization of the oral biofilm, its maturation, and the microbial mediated caries processes remains incomplete. These organisms colonize the oral cavity prior to or shortly after the eruption of the first tooth.

The infant's oral cavity is often infected with *S. mutans* by transmission from a caregiver, usually the mother. Children colonized by *S. mutans* by the age of 2 years are much more likely to experience early childhood caries than children lacking cultivable *S. mutans*.³⁻⁵

Dental enamel is composed primarily of hydroxyapatite with smaller amounts of water, protein, and trace elements including fluoride. The enamel of newly erupted teeth is less dense and more permeable and

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soluble than mature enamel. The AEP assists in the post-eruptive maturation of the dental enamel, considerably reducing its porosity. The application of topical fluoride to newly erupted teeth can also significantly increase caries resistance.^{6,7}

The Process

The mineral composition and structure of the enamel surface are partially products of the dynamic demineralization and remineralization process. The dental biofilm modulates the tooth surface pH impacting this process. Dietary ingestion of fermentable carbohydrates, especially sucrose, provides the substrate for the cariogenic microorganisms in the biofilm to form organic acids. The enamel demineralization process begins when these acids lower the pH of the biofilm to below 5.5. The acids result in the loss of calcium and phosphates from the surface and subsurface enamel into the AEP and biofilm, creating a white spot lesion. A white spot lesion is characterized by low calcium and phosphate content and is the initial detectable evidence of enamel demineralization in the subsurface region of the tooth. The white spot lesion will progress into frank cavitation if the bacterial plaque is not regularly removed from the tooth surface.⁸

The demineralization process is reversible provided that the acidogenic properties of the biofilm are neutralized. The buffering capacity of saliva plays a critical role in helping restore a neutral pH at the tooth surface. Remineralization occurs when the dietary carbohydrate is removed and the pH of the biofilm is raised to approximately 7.0. Once the pH returns to higher than the critical point, demineralization is arrested and minerals can be added back to the partially dissolved enamel crystallites.

Treatment of early caries by remineralization has the potential to significantly advance noninvasive clinical management of the disease. Calcium and phosphate in the saliva and plaque permit the recovery of some lost mineral content by the enamel. Extremely high calcium and phosphate concentrations in the dental pellicle can actually adversely affect the quality of re-mineralization.⁹ High concentrations favor formation of calcium-phosphate mineral phases on the surface that occlude the enamel pores and limit remineralization of the subsurface enamel. A more complete remineralization process occurs when the calcium and phosphate are lower.^{3,10} Laboratory research suggests that caries extending into the dentin can also be remineralized.¹¹

Fluoride

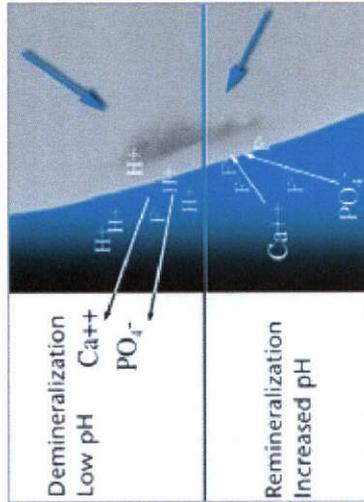


Figure 1: Demineralization-remineralization process.

Fluoride is the most reactive element in the periodic table and its presence in the biofilm is important in limiting demineralization and stimulating remineralization of the hydroxyapatite crystal. Fluoride ions react with the partially dissolved enamel crystallites and attract calcium and phosphate ions in the saliva to the demineralized dental enamel. This enhances new mineral deposition and crystallite re-growth. In addition, the presence of fluoride favors the formation of enamel fluorapatite by substitution of hydroxyl molecules with fluoride in the hydroxyapatite crystal. Fluorapatite is harder and more resistant to acid dissolution than hydroxyapatite.

Frequent exposure of the teeth to low concentrations of fluoride is thought to produce the optimal remineralization environment. This can be achieved by the regular ingestion of fluoridated drinking water due to its topical effects, daily use of over-the-counter oral rinses containing 0.05% sodium fluoride, fluoride-containing chewing gum, and the regular use of fluoride-containing dentifrice.¹²

Periodic, professionally-applied topical fluoride agents can also be beneficial. The American Dental Association has approved the use of 1.23% acidulated phosphate fluoride (APF) gel/foam, 8% stannous fluoride solution, and 2% sodium fluoride gel for professionally applied topical agents.

European studies of a 5% sodium fluoride varnish have also demonstrated caries preventive benefits similar to APF gel/foam when applied topically to the teeth.^{13,14} Because similar studies have not been replicated in the United States, fluoride-containing varnish is only approved for use as a cavity liner and treatment of hypersensitivity by the Food and Drug Administration. However, fluoride-containing varnishes are widely used "off-label" for topical application as caries prevention agents.¹⁵

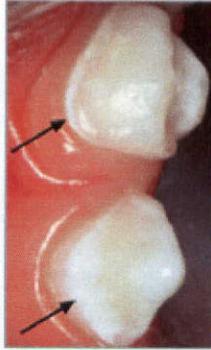


Figure 3: White spot lesions that are candidates for remineralization.

Calcium, phosphate, and fluoride ions in the saliva assist in the remineralization process (Figure 1). Saliva is the vehicle that delivers available fluoride ions to the demineralized enamel and partially dissolved crystallites.¹⁶ The predominant enamel/ fluoride reaction products from topical fluoride are CaF_2 and $\text{CaH}(\text{PO}_4)$ ¹⁷ (Figure 2). Without saliva to slowly dissolve the CaF_2 and deliver the fluoride ion to the demineralized enamel, the remineralization process will not occur. The topical application of aqueous stannous fluoride solution to the teeth is effective in preventing dental caries but may not encourage the remineralization process as well as other topical fluoride products. This is attributed to the deposition of tin ions from the stannous fluoride on the enamel surface. These ions can occlude the porous enamel thus reducing the bioavailability of the fluoride ions to the demineralized crystallites.

Calcium Phosphate

Remineralization may be a noninvasive treatment of early carious lesions and hypomineralized enamel

negating the need for invasive dental restorations. The development of products to encourage remineralization is a research goal. Currently, there are three types of remineralization technologies available.

Amorphous calcium phosphate (ACP) is a reactive and soluble calcium phosphate compound that releases calcium and phosphate ions to convert to apatite and remineralize when it comes in contact with saliva. Forming on the tooth enamel within the dentinal tubules, ACP provides a reservoir of calcium and phosphate ions in the saliva.¹⁸

Calcium sodium phosphosilicate (NovaMin[®]) contains calcium, phosphorous, sodium, and silica. It reacts with saliva, releasing Ca^{2+} , P^{5+} , and Na^+ into the oral environment. First the Na^+ buffers the acid and then the charged Ca^{2+} and P^{5+} ions saturate saliva precipitating into demineralized areas to form a new layer of hydroxy apatite filling the demineralized lesions.¹⁹

Casein phosphopeptides (CPP) is a sticky, milk-derived protein that binds to ACP and bacterial plaque. It stabilizes amorphous calcium phosphate (ACP). Products have recently been introduced containing CPP-ACP or Recaldent[™] that use CPP as a vehicle to deliver and maintain a super-saturation state of ACP at or near the tooth surface. Laboratory and limited clinical trials of a professionally- or patient-applied topical CPP-ACP paste show promise in slowing the progression of demineralization and promoting remineralization of white spot lesions²⁰⁻²² (Figure 3). Some of these products also contain fluoride. Gum, lozenges, and topically applied solutions containing CPP-ACP may also remineralize white spots.^{23,24}

Sealants

Sealants are often used to occlude at-risk pits and fissures on teeth. When properly placed, sealants provide a physical barrier between the dental enamel and the oral environment shielding the tooth surface from acid challenge. Sealants are effective in arresting caries progression when properly applied to incipient demineralized lesions.²⁵ Fluoride-releasing sealants are also on the market. The manufacturers of fluoride-releasing sealants claim that their products promote remineralization by releasing fluoride in the immediate area adjacent to the sealant.

Chewing Gum

The importance of saliva's buffering capacity in the remineralization of demineralized hard dental tissues and the maintenance of optimum oral health is well established. Recently there has been renewed interest in the benefits of chewing gum as a means to stimulate saliva flow to prevent dental caries.²⁶⁻²⁸ Contraction of the mastication muscles increases the flow of saliva, resulting in an elevated presence of calcium and phosphate ions, and it raises the pH of the biofilm. All of these traits are important to the

remineralization process. Numerous studies have demonstrated the caries-preventing qualities of frequent use of chewing gum sweetened by dietary sugar alcohols such as xylitol and sorbitol.^{29,30} Chewing gum, particularly sugar-free gum, may offer a valuable adjunct to a caries prevention and remineralization program.

Conclusions

The caries process is a continuum of many cycles of demineralization and remineralization. Remineralization is the body's natural process for repairing subsurface non-cavitated carious lesions caused by organic acids created by bacterial metabolism of fermentable carbohydrates. Fluoride ions in the presence of calcium and phosphate promote remineralization by building a new surface on existing crystal remnants in subsurface demineralized lesions. This environment also favors the formation of the more favored fluorapatite crystal in the enamel.

Remineralization of incipient carious lesions is a conservative alternative to conventional caries removal and dental restoration. The development and promotion of a robust caries prevention and remineralization regimen that discourages demineralization and encourages remineralization remains a challenge. Additional research is needed to identify new approaches to stimulate the beneficial effects of the remineralization process, reduce the incidence of dental caries and to optimize health.



Michael W. Roberts, DDS, MScD, is the Henson Distinguished Professor and associate chair of the Department of Pediatric Dentistry at the University of North Carolina School of Dentistry (UNCSD), Chapel Hill. He has published more than 90 refereed papers in professional journals and contributed to several dental text and reference books. Roberts' research interests include oral effects and management of eating disorders in adolescents and the use of lasers in pediatric dentistry. He is a past examiner and president of the American Board of Pediatric Dentistry.



J. Timothy Wright, DDS, MS, is the James W. Bawden Distinguished Professor and chair of the Department of Pediatric Dentistry at UNCSD. His research interests include the diagnosis and treatment of developmental defects in teeth resulting from hereditary and environmental conditions, and the understanding of normal tooth development. Wright has received numerous National Institutes of Health research grants to support his work. To date, he has more than 135 publications in refereed journals. He has an active pediatric dentistry private

practice that includes patients with special medical and oral health care needs.

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From *Dimensions of Dental Hygiene*. July 2009; 7(7): 16, 18, 20-21.

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SPECIAL CARE IN DENTISTRY



Special Care in Dentistry

Volume 23 Issue 5, Pages 177 - 179

Published Online: 12 Mar 2008

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The use of topical fluoride to prevent or reverse dental caries

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KEYWORDS

Dental caries/prevention • control; • fluorides • topical; • mouthwashes

ABSTRACT

Topical fluoride has been the main stay of caries prevention for many decades. There are several mechanisms which make it beneficial including **inhibiting demineralization, enhancing remineralization,** and inhibiting bacterial growth. Topical fluoride is available in many different forms. The concentrations of various fluoride preparations range from 225 parts per million (ppm) fluoride in over-the-counter oral rinses to 22,600 ppm in the fluoride varnishes. The clinician must decide which type of topical preparation is best suited for their patient. Patients with high caries risk may benefit from prescription strength fluorides (along with the other chemical and dietary therapies described in this issue of *Special Care in Dentistry*). The application of fluoride varnish is an excellent topical form for those patients who have access to dental care and for whom it is difficult to comply with the use of other topical forms.

DIGITAL OBJECT IDENTIFIER (DOI)

10.1111/j.1754-4505.2003.tb00308.x [About DOI](#)

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Effect of different fluoride concentrations on remineralization of demineralized enamel: an in vitro pH-cycling study

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This study was supported by the Research Fund of The University of Istanbul (Project number: B-539/16062000).

Summary

Objectives. The purpose of this study was to determine the effects of three different fluoride mouth rinses (226, 450 and 900 ppm) in comparison to non-fluoride application group (control group) on demineralized enamel under in vitro pH-cycling conditions.

Methods. Initial demineralization was obtained by acetic acid for 24 hours. After remineralization for 11.5 h, pH-cyclis was as follows: demineralization with acid solution for 30 min., application of NaF (control (0), 226, 450 and 900 ppm F⁻) for 2 min. and remineralization for 11.5 h. This procedure was applied twice. This 24-hour cycling application was repeated for 28 days. Vickers microhardness measurements were conducted at the beginning, after the initial demineralization and after 3, 7, 14 and 28 days pH-cycling applications.

Results. Remineralization begins after 14 days in all groups (Wilcoxon, $p > 0.05$). Only the group with 226 ppm fluoride reached the beginning microhardness ($p > 0.05$).

Conclusions. It was concluded that regular daily use of fluoride solutions with 226 ppm F⁻ enhanced remineralization in the pH-cyclis environment and reached the beginning microhardness. Demineralization did not continue in any fluoride treatment group, even in the control group.

Key words: fluoride, demineralization, remineralization, pH-cycling, microhardness.

Introduction

Enamel is consistently exposed to de-/remineralization in oral conditions. There is a delicate balance between demineralization and remineralization [1, 2]. The interruption of this balance results in caries, where fluoride is the most commonly used agent for „healing“ of the initial process. The presence of fluoride in saliva and plaque, during a cariogenic challenge, can inhibit the dissolution of enamel crystals and subsequently enhance remineralization. But additional fluoride applications are mostly recommended. Mouth rinses, gels or varnishes are preferred to enhance the remineralization and reduce the demineralization [1, 3, 4]. Enamel de-/remineralization processes were studied previously in vitro [3, 5, 6] and in vivo [7-9]. De-/remineralization processes have been tested by polarized light microscopy (PLM) [10], elec-

tron microscopy [11], quantitative microradiography (MRG) [6, 10, 12, 13], surface microhardness (Knoop, Vickers) [12, 14, 15], iodide permeability (Ip) [15] and calcium and fluoride analysis [13].

Previous studies have evaluated the fluoride efficacy of oral hygienic products, such as tooth-pastes or [10,16-20] mouth rinses [21-24].

The purpose of this study was to determine the effects of three different fluoride mouth rinses (226, 450 and 900 ppm) in comparison to non-fluoride application group (control group) on in vitro enamel demineralization under pH-cycling conditions.

Materials and Methods

Preparation of the tooth slabs: 28 caries free premolars extracted for orthodontic reasons were used in this study. Teeth were sectioned into two enamel slabs in the mesio-distal direction. The

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vestibular side of each tooth was embedded in epoxy resin with the enamel surface parallel to the resin block surface. Enamel slabs were ground with 320, 600 and 1200 grade silicon carbide discs and polished with aluminum paste. A 4 mm x 3 mm test area was obtained in the center of the specimen. These samples were randomly assigned into four groups (group 1, 2, 3 and control group) (n = 7).

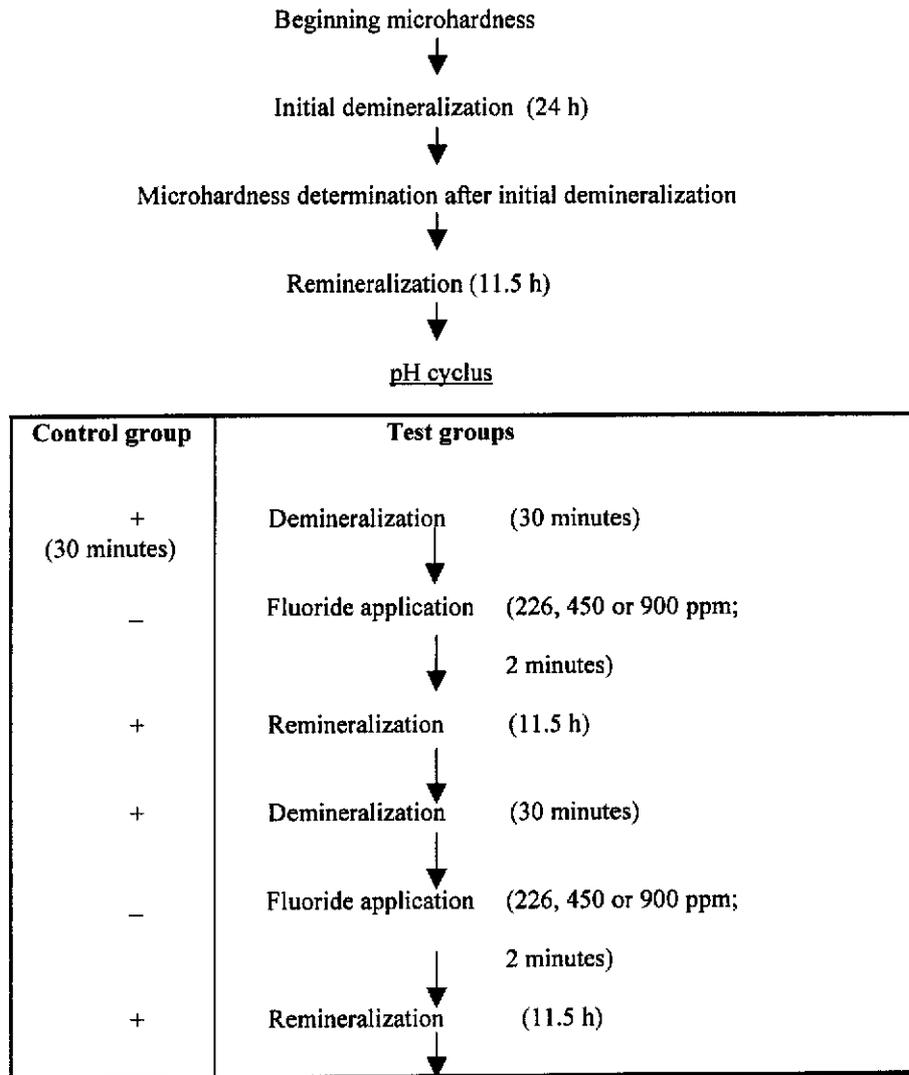
Experimental design employed in this study is shown in *Figure 1*.

Experimental solutions:

- demineralization solution; it contained 2.2 mM/L CaCl₂, 2.2 mM/L KH₂PO₄ and 50 mM/L acetic acid, and the pH was adjusted to 4 with KOH. This solution was used to form the initial enamel lesion and was also applied for 30 minutes for daily demineralization [6].

- remineralization solution; it contained 1.5 mM/L CaCl₂, 0.9 mM/L KH₂PO₄ and 130 mM/L KCl, with pH adjusted at 7 [6].

- fluoride solutions contained NaF with concentrations of 226 ppm F⁻ (Group 1), 450



Microhardness determination after 3, 7, 14, 28 days

Figure 1. Experimental design

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ppm F⁻ (Group 2) and 900 ppm F⁻ (Group 3). All solutions were freshly prepared every day.

Experimental process: (Figure 1)

For initial enamel demineralization, enamel slabs were stored in demineralization solution for 24 h and remineralized for 11.5 h. The pH-cyclus model started with a demineralization for 30 minutes. The experimental samples were treated with fluoride solutions for 2 minutes followed by remineralization for 11.5 h. This procedure was repeated twice. This cyclus was repeated for 28 days.

Microhardness testing:

Enamel microhardness was tested by a microhardness tester (Japan) with a Vickers diamond indenter loaded with 200 gr and applied for 10 seconds. The mean of five hardness measurements made at 35 μ m intervals was used as representative Vickers Hardness Number (VHN). The diagonal length of the indentation was measured and converted to VHN.

Microhardness measurements were performed at the beginning, after the 24-h initial demineralization, and after the 3rd, 7th, 14th, and 28th day.

Statistical analysis:

Friedman and Wilcoxon tests were used to compare the significance of differences within the

groups. Comparison between the groups was analyzed using Kruskal-Wallis test.

Results

Table 1 shows the mean and standard deviation of VHN values for group 1, 2, 3 and the control group. Table 2 shows statistical analysis of the differences in microhardness values at various stages of the experiment (3rd, 7th, 14th and 28th day).

Microhardness values of the sound and the demineralized enamel:

No significant differences were observed among the microhardness values for all groups at the beginning. Microhardness values of enamel slabs after demineralization did not show any difference among the groups. Important differences were noted for microhardness values between the beginning and after initial demineralization in all groups ($p < 0.05$). Microhardness values after initial demineralization were not significantly different, which is important for the standardization of the study.

Microhardness measurements at the 3rd and 7th days:

No significant increase in hardness was observed in fluoride and control groups after the 3rd and the 7th days ($p > 0.05$) (Table 2).

Table 1. The mean and standard deviation (SD) of Vickers microhardness (VHN) value in the groups

Groups		VHN at the beginning	VHN after initial demineralization	VHN after 3 rd day	VHN after 7 th day	VHN after 14 th day	VHN after 28 th day
control (0 ppm)	mean	368.54	305.20	319.42	319.52	323.22	31.94
	SD	11.08	23.94	18.12	8.32	21.01	16.26
group 1 (226 ppm F ⁻)	mean	366.51	305.11	320.20	328.14	340.11	354.00
	SD	10.351	25.18	31.93	33.31	26.36	28.19
group 2 (450 ppm F ⁻)	mean	368.40	304.85	309.05	315.94	325.42	340.08
	SD	8.42	21.15	17.09	17.20	11.30	15.03
group 3 (900 ppm F ⁻)	mean	365.80	302.48	310.57	319.65	327.34	342.54
	SD	9.70	22.08	17.54	15.16	19.93	19.93

Table 2. Statistically analyses of differences within groups

	Friedman		Demin 3 rd day	Demin 7 th day	Demin 14 th day	Demin. 28 th day	Beginning 28 th day
	X ²	p	p	p	p	p	p
control	23.19	0.0005	0.093	0.116	0.028*	0.018*	0.018*
group 1	27.00	0.0005	0.091	0.063	0.018*	0.018*	0.173
group 2	27.54	0.0005	0.499	0.176	0.028*	0.018*	0.018*
group 3	25.36	0.0005	0.735	0.091	0.018*	0.018*	0.028*

*: significant according to Wilcoxon test ($\alpha: 0.05$)

Microhardness measurements at the 14th day:

The microhardness values in the fluoride and control groups were significantly different in comparison to the demineralized enamel after the 14th day ($p < 0.05$). All groups were remineralized after 14 days (*Table 2*), but did not reach the beginning microhardness.

Microhardness measurements at the 28th day:

The remineralization of all groups continued until the 28th day ($p < 0.05$). The obtained results at the 28th day showed that only group 1 (226 ppm F⁻) reached beginning microhardness measurements ($p > 0.05$, *Table 2*). Group 2 and 3 did not show any differences related to the control group ($p > 0.05$).

Discussion

The present study was designed to determine the period of the expected remineralization under continuous pH conditions.

Simulation of the natural mouth environment forces the researchers to use pH-cycling techniques [25]. Different modifications of this technique have been applied for investigating caries processes and effect of caries preventive agents [10, 16, 17, 26, 27]. Therefore, pH-cyclis creating models can be accepted as a good evaluating method of the caries process and also provide standard study conditions. Because of these reasons, the present research was designed on a pH cycle and determined the effects of three different fluoride mouth rinses in comparison to non-fluoride application group (control group) on in vitro demineralized enamel. In this study, the experimental set-up was arranged in such a way that it simulated an oral environment subjected to acid and remineralization twice a day. In order to accomplish this, cariogenic acid, fluoride and remineralization solutions were applied on the initially demineralized sample surfaces.

NaF is a preferred agent for caries investigations [3, 17, 18]. Therefore, in this study the fluoride treatment solutions were prepared with NaF. Fluoride applications (2 minutes) were used twice daily. The fluoride concentrations used in our study (226 ppm, 450 ppm and 900 ppm) are identical to the concentrations of fluoride rinses, which are clinically recommended (0.05%, 0.1% and 0.2% NaF solutions).

It was reported that microhardness profiles could be used for comparative measurements of hardness changes of dental hard tissue [12, 14, 15, 17, 21, 24]. A microhardness evaluation was fulfilled in this study.

Kodaka et al. evaluated the correlation between microhardness and mineral content in sound human enamel [28]. The study concluded that microhardness values do not reflect small differences in the mineral and organic contents of sound enamel, but are indications of gross changes, as observed in enamel caries.

Zero et al. indicated that both Ip test and surface microhardness (SMH) test had sufficient sensitivity to detect the very early stages of enamel demineralization [15]. The coating of the enamel pores with calcium fluoride layer can affect Ip test whereas SMH test is not affected by it.

Many authors have investigated fluoride concentration and efficacy of fluoride application.

White reported that there was an increase in remineralization and in the resistance of enamel against acid when toothpastes with sodium fluoride (0.243% F⁻) and amine fluoride (0.34% F⁻) were used [5].

Featherstone et al. showed that the maximum remineralization efficacy of fluoride was at 550-600 ppm F⁻ [29].

Damato et al. searched for the effects of NaF solutions on the artificially carious enamel using different concentrations [30]. Their results have shown that remineralization was high in the 500 ppm F⁻ group, but there was no additional remineralization when higher fluoride concentrations were applied.

Lammers et al. studied the effect of remineralizing solutions with or without 2 ppm F⁻ on the remineralization of bovine enamel with artificial subsurface lesions. However, these investigators did not use a pH-cycling model in their in vitro study. The group applied with fluoridated solution showed less remineralization in comparison to the nonfluoride group. They explained this finding by the inhibitory effect of fluoride at certain concentrations on the crystal growth [31].

Tagaki et al. reported that an in vitro pH-cycling model was used to evaluate the potential anti-caries effects of 13.2 and 52.6 mmol/l NaF and 3 mmol/l F⁻ two-component rinses. They observed that two-component rinses with 3 mmol/l F⁻ provided a degree of demineralization protec-

tion equal to a 13.2 mmol/l NaF (250 ppm F⁻) rinse [32].

The importance of the frequency and period of application of fluoride rinses have also been investigated.

Kirkham et al. suggested that the degree of de-/remineralization increased with frequency of acid challenge [33].

Stephen reported that the frequency of fluoride rinsing is more important than the concentration of fluoride [18].

In our study, three different fluoride concentrations were used on the initially demineralized enamel and pH changes were simulated for 28 days. It was also determined that the frequency is more important. There was no significant increase in the microhardness values after 7 days. The remineralization of initially demineralized enamel needs more than 7 days, under continuous demineralization conditions (periods of 30 minutes, twice daily). The 14th day measurements showed that remineralization occurred in all groups. After the end of the cyclis only the group with 226 ppm reached the beginning microhardness. Due to the methodological differences between the pH-cycling studies, other researches cannot be compared or related directly with our study.

The present study showed that 226 ppm fluoride application is sufficient for remineralization, and there is no need to increase the concentration.

Remineralization is observed clinically as the disappearance of white spot lesions. It was reported that remineralization occurs during caries development [34]. The application of low concentrated fluoride products have been recommended to the individuals who have a high risk of tooth decay, white spot or initial enamel erosion lesion [2, 4].

High concentrated fluoride solutions form a calcium fluoride or calcium fluoride-like substance. These substances may act as a reservoir of fluoride in pH changes in oral conditions [1, 3, 35]. Another approach is that CaF₂ blocks the diffusion of ions into the enamel and fluoride cannot reach the subsurface lesion [10]. In toothpastes, due to the high fluoride concentration (1000-1500 ppm), a CaF₂ like substance may occur in plaque, on mucosal surface, on enamel surface or inside the caries-like lesions [1-3]. Studies show that remineralization of deep

lesions is experimentally possible in both enamel and the underlying dentin [36]. Under in vivo conditions, the presence of precipitation inhibitors (e.g. salivary proteins, pyrophosphates or diphosphanates) in saliva might affect diffusion and precipitation through inhibition of crystal growth [34, 36]. The CaF₂ or CaF₂-like layer may be the explanation why additional remineralization did not occur with higher fluoride concentration (450 or 900 ppm) in our study.

In the present study, remineralization was observed in all groups, even in the control group, in spite of the demineralization periods. These findings are in agreement with Meyerowitz et al. intra-oral appliance model [21].

Clinically, continuous low pH, frequency of the cariogenic diet, saliva composition, saliva flow rate, salivary clearance, salivary buffering capacity, oral health habits, effectiveness of tooth brushing and the periodontal condition are important factors in caries activity. Additional fluoride application, such as mouth rinses, fluoridated chewing gums, professional fluoride applications should be recommended individually after detailed history and determination of the oral condition through caries activity test, saliva pH and other individual criteria. Recalls and carious activity tests can modify the recommendations for oral care.

According to the findings obtained, no relationship exists between the fluoride concentration and remineralization enhancement. The 226 ppm fluoride treatment group showed the best „healing“ in this study. The regular daily use of the fluoride mouth rinses with low fluoride concentration might enhance remineralization and play a role for reaching the beginning microhardness under continuous demineralization conditions.

Conclusions

It was concluded that the 226 ppm fluoride application is sufficient for the remineralization, and there is no need to increase the concentration under pH-cycling conditions. The regular daily use of 226 ppm F⁻ enhances the remineralization under pH-cyclis environment and reached the beginning microhardness after 28 days. Demineralization did not continue in any fluoride treatment group, even in the control group.

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ORIGINAL ARTICLE

Year : 2010 | Volume : 13 | Issue : 1 | Page : 42-46

Remineralization potential of fluoride and amorphous calcium phosphate-casein phospho peptide on enamel lesions: An *in vitro* comparative evaluation

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Date of Submission	05-Jun-2009
Date of Decision	15-Aug-2009
Date of Acceptance	07-Sep-2009
Date of Web Publication	20-Apr-2010



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Abstract

Aim: This *in vitro* study was conducted on enamel blocks of human premolars with the aim of evaluating the remineralization potential of fluoride and ACP-CPP and the combination of ACP-CPP and fluoride on early enamel lesions.

Materials and Methods: Fifteen intact carious free human premolars were selected. The coronal part of each tooth was sectioned into four parts to make 4 enamel blocks. The baseline SMH (surface microhardness) was measured for all the enamel specimens using Vickers microhardness (VHN) testing machine. Artificial enamel carious lesions were created by inserting the specimens in demineralization solution for 3 consecutive days. The SMH of the demineralised specimens was evaluated. Then the four enamel sections of each tooth were subjected to various surface treatments, i.e. Group 1- Fluoride varnish, Group 2- ACP-CPP cream, Group 3- Fluoride + ACP-CPP & Group 4- Control (No surface treatment). A caries progression test (pH cycling) was carried out, which consisted of alternative demineralization (3hours) and remineralization with artificial saliva (21 hours) for five consecutive days. After pH cycling again SMH of each specimen was assessed to evaluate the remineralization potential of each surface treatment agent. Then, to assess the remineralization potential of various surface treatments at the subsurface level, each enamel specimen was longitudinally sectioned through the centre to expose the subsurface enamel area. Cross-sectional microhardness (CSMH) was evaluated to assess any subsurface remineralization

Results: Statistical analysis using one-way ANOVA followed by multiple comparisons test was applied to detect significant differences at $P \leq 0.05$ levels between various surface treatments at different phases.

Conclusions: Within the limits, the present study concludes that; ACP-CPP cream is effective, but to a lesser extent than fluoride in remineralizing early enamel caries at surface level. Combination of fluoride and ACP-CPP does not provide any additive remineralization potential compared to fluoride alone. Fluoride, ACP-CPP and their combination are not effective in remineralizing the early enamel caries at the subsurface level.

Keywords: ACP-CPP; demineralization-remineralization; fluoride

Introduction

A carious lesion begins with the establishment of a combination of specific bacterial population, which is capable of demineralizing enamel under specific modified environment in the oral cavity. This demineralization is clinically manifested as a white, opaque spot particularly when air-dried.

In a neutral environment, the hydroxyapatite of the enamel is in equilibrium with saliva which is saturated with calcium and phosphate ions.^[1] At or below pH 5.5, H⁺ ions produced by the bacterial metabolites react preferentially with the phosphate group of the enamel crystals, converting PO₄²⁻ ion to (HPO₄)²⁻ ion which, once formed, can no more form the crystal lattice; at the same time H⁺ ions are buffered. This leads to enamel dissolution, termed as demineralization, which marks the beginning of early enamel caries.^{[2],[3]}

However, the demineralization can be reversed if the pH is neutralized and there are sufficient calcium and phosphate ions available in the immediate environment. This enables the rebuilding of partly dissolved apatite crystals. This is called as remineralization. To restore the natural equilibrium, either remineralization must be enhanced or demineralization must be retarded. The early enamel lesions have a potential for remineralization, with an increased resistance to further acid challenge, particularly with the use of enhanced remineralization treatments.

Fluoride is the most commonly used remineralizing agent. When the acid attacks the enamel surface, the pH begins to rise and fluoride present in the microenvironment causes enamel dissolution to stop.

As the pH rises, new and larger crystals that contain more fluoride (fluorhydroxyapatite) form, thereby, reducing the enamel demineralization by forming fluorhydroxyapatite crystals and enhancing remineralization. Normally, remineralization by fluoride is a self-limiting surface phenomenon that prevents penetration of ions into the depth of the lesion.^[4] Rapid deposition of fluorapatite forms a firm surface layer, which is more resistant to further demineralization. However, at the same time, it is resistant to penetration of calcium and phosphate ions required to rebuild the lesion in depth.

A new remineralization technology based on phosphopeptide from milk protein casein has been developed. The casein phosphopeptides (CPP) contain multiphosphoserine sequences with the ability to stabilize calcium phosphate in nanocomplexes in solutions like amorphous calcium phosphate (ACP). Through their multiple phosphoserine sequences, CPP binds to ACP in metastable solution preventing the dissolution of calcium and phosphate ions. The ACP-

CPP also acts as reservoir of bio-available calcium and phosphate, and maintains the solution supersaturated, thus facilitating remineralization.^[5] Studies report that unlike fluoride, ACP-CPP has been shown to remineralize enamel subsurface and subsurface lesion *in vivo* and *in vitro*.^{[6],[7]} It is expected that combination of fluoride and ACP-CPP would give enhanced remineralization compared to individual application of fluoride and ACP-CPP. This *in vitro* study aims to evaluate the remineralization potential of fluoride varnish, ACP-CPP, and combination of fluoride +ACP-CPP on early enamel lesions.

Materials and Methods

The materials used in the study;

1. Fluoride varnish (Fluoroprotector Intro pack; Ivaclar Vivadent)
2. Amorphous calcium phosphate- Casein phosphopeptide (CPP-ACP) GC Tooth Mousse, Recaldent; GC Corp; Japan

Fifteen premolars extracted from patients ranging in the age group of 14-20 years, for orthodontic purpose, were collected and the radicular part of each tooth was removed. The coronal part of each tooth was then longitudinally sectioned bucco-lingually and mesio-distally into four sections using a high speed diamond tipped disc. Four enamel specimens were prepared. Custom made plastic cylindrical molds were made and self cured acrylic resin was poured on it; then each enamel block was embedded in, on top of partially set, and allowed to set. An acid resistant nail varnish was applied around the exposed enamel surface leaving a window of 3 mm X 3 mm of enamel exposed at the centre.

Lieca Japan, Tokyo, Vickers micro hardness tester was used to evaluate micro hardness. A load of 25 grams was applied, for five seconds, for all the specimens. The micro hardness numbers (VHN) of five indentations at spacing of 100 microns were taken and the average value was considered the mean base line micro hardness (SMH) of the corresponding specimen. The objective of base line surface micro-hardness determination is to compare and calculate the changes that occur after induction of enamel lesions and after pH cycling.

Carious lesions representing preliminary stage of subsurface enamel demineralization were produced by suspending four sections of each tooth into glass tubes containing 20 ml of demineralization solution, for 72 hours, in an incubator at a temperature of 35 degree.^[8] After induction of enamel lesions, all the specimens were evaluated for surface micro hardness measurements under 25 gram loads for five seconds duration.

The composition of the demineralizing solution was as follows;

$\text{CaCl}_2 = 2.2 \text{ mM}$ $\text{NaH}_2 \text{PO}_4 = 2.2 \text{ mM}$ Lactic acid = 0.05 M

Fluoride = 0.2 ppm, Solution was adjusted with 50% NaOH to a pH 4.5

Four sections of each tooth were subjected to the following surface treatments,

Section 1- A thin layer of fluoride varnish was applied, allowed to be absorbed for 20 seconds and then air dried.

Section 2- A generous layer of ACP-CPP cream was applied by an applicator brush and left undisturbed for a minimum of three minutes.

Section 3- A thin layer of fluoride varnish was applied and allowed to be absorbed for 20 seconds. This was followed by a generous layer of ACP-CPP cream and left undisturbed for a minimum of three minutes.

Section 4- This served as the control group where no surface treatment was performed.

A pH cycling regimen included alternative demineralization (three hours) and remineralization (21 hours) for five consecutive days. For the demineralization phase, the demineralization solution used for the induction of enamel lesions was used and for the remineralization phase, a synthetic saliva preparation was carried out.^[9]

The inorganic composition of synthetic saliva is similar to that of natural saliva. After pH cycling, again the surface micro hardness was assessed for all the specimens under 25-gram load for 5 seconds.

This composition of the synthetic saliva is as follows :

Na₃ PO₄ - 3.90 mM NaCl₂ - 4.29 mM KCl - 17.98 mM

CaCl₂ - 1.10 mM MgCl₂ - 0.08 mM H₂ SO₄ - 0.50 mM

NaHCO₃ - 3.27 mM, distilled water, and the pH was set at a level of 7. 2.

Each specimen was longitudinally sectioned into two halves through the center of the window. The cut surface was exposed and polished. A row of five indentations was made at approximately 100 microns below the enamel surface. All the sections were evaluated for the measurement of cross-sectional micro hardness (CSMH) which denoted the changes in micro hardness at subsurface level under the same parameter of load and time. Then the percentage of mineral recovery of the surface micro hardness values was determined by a formula,

% SMHR = Percentage of Surface Micro Hardness Recovery

$$\frac{\text{Initial Enamel IE} - \text{Demineralized Enamel DE}}{\text{Treated enamel TE} - \text{Demineralized Enamel DE}} \times 100$$

Results

Statistical analysis using one-way ANOVA followed by multiple comparisons test (multiple Duncan test)) was applied to detect significant differences at the level of $p \leq 0.05$, between various surface treatments at different phases of study.

Discussions

Clinically, the early enamel lesion appears white because the normal translucency of the enamel is lost. The surface becomes fragile and is susceptible to damage from probing. The most important feature of white spot lesion is the presence of relatively intact surface layer overlying subsurface demineralization (40-70%). Even though initial enamel lesions have intact surfaces, they have a low mineral content at the surface layer when compared to sound enamel; thus showing a lower hardness value at the surface than for sound enamel tissue. [10],[11]

Organic acids are produced by the metabolic activity of micro organisms in the bacterial plaque. These acids diffuse through the pellicle into the surface enamel. These acids attack the apatite crystals, particularly at the vulnerable lattice points where carbonate ions are present. This causes Ca^{2+} , OH^- , PO_4^{2-} , F^- , CO_3^- , Na^+ and Mg^{2+} to be removed from the crystal lattice and to diffuse into the solution phase between the crystals. The dissolving calcium ions and phosphate ions form various calcium phosphate salts that either diffuse to the exterior or provide an environment that facilitates the repair of the faulty crystallites beneath the surface of enamel facilitating remineralization. [12] Mineral loss or demineralization proceeds as long as sufficient acid is available. As more enamel dissolves, concentration of the Ca ion and PO_4 ion increases.

As calcium and phosphate ions diffuse outwards, remineralization at the surface becomes more and more likely. This leads to the formation of an apparently intact enamel surface layer about 20-40 microns where the mineral content is higher than the body of the lesion. In the present study, the specimens kept in the demineralization solution (CaCl_2 , NaH_2PO_4 , Lactic acid and Fluoride) for 72 hours at 37°C created a subsurface demineralization of approximately 150 microns width with an intact surface simulating an early enamel lesion. [13] The concentration of both calcium and phosphates, in the demineralization solution, was at 50% of saturation level, causing dissolution of only enamel subsurface. Addition of fluoride prevented surface demineralization by forming fluorapatite at the surface, which simulated the naturally occurring early enamel lesions having intact surface layer.

Considering the importance of the surface layer in caries progression, the evaluation of changes in this region is relevant. Surface micro hardness (SMH) measurement is a suitable technique for this purpose. Micro hardness measurement is appropriate for a material having fine microstructure, non-homogenous or prone to cracking like enamel. Surface micro hardness indentation provides a relatively simple, non-destructive and rapid method in demineralization and remineralization studies. Therefore, in the present study, the micro hardness values for each specimen were measured in three steps; the base line micro hardness, after induction of carious lesion (demineralization) and after pH cycling. The values (VHN) obtained during the initial base line micro hardness measurements in the present study were in the range of VHN 254 - 363, which satisfies the VHN range of normal enamel tissue. [14] The surface micro hardness values for each group of the enamel specimens were decreased to 162-183 at the end of 72 hours of demineralization [Table 1] which is in accordance with the study conducted by Maupome *et al.* [15]

The period for demineralization in the pH cycling phase is for three hours, which was to simulate the duration of demineralization (low cariogenic challenge) that occurs in the oral cavity. [16] The test material was applied on enamel blocks twice a day s to simulate the normal recommended daily oral prophylaxis. In the present study, after the pH cycling phase the mean SMH (VHN) for Fluoride group 218.30, for ACP-CPP group 185.20, for Fluoride + ACP-CPP group 216.25 and for the control group 167.30 respectively. It indicates that combination of fluoride + ACP-CPP does not provide any additive remineralization potential when compared to fluoride varnish alone. The mean increase in SMH (VHN) for ACP-CPP

treatment group is 185.20, which indicates that there is a significant increase in micro hardness. Therefore, ACP-CPP can also aid in remineralization, [17],[18],[19],[20],[21] but not as effectively as fluoride or fluoride and ACP-CPP group combination.

Moreover, in the fluoride + ACP-CPP treatment group, the fluoride varnish was applied first followed by the application of ACP-CPP over the enamel specimens. It is speculated that the results obtained in fluoride + ACP-CPP group reflect the results similar to fluoride varnish and hence might have hindered the effect of ACP-CPP. The varnish applied evaporated quickly to form a thin film on surface. The ACP-CPP group, being creamy in consistency, could not properly wet the surface.

It is speculated that most of the ACP-CPP cream was lost after washing in distilled water. The percentage of surface micro hardness recovery was calculated for all surface treatment groups, which showed greatest recovery for the fluoride + ACP-CPP group (35%) followed by fluoride (32%), followed by ACP-CPP (17%) [Graph 1]. There was no regain in micro hardness in the control group giving a negative sign (-14%). The difference in the percentage micro hardness recovery in fluoride group and fluoride + ACP-CPP group was not statistically significant. The mean CSMH (VHN) values obtained were: 148.87 (fluoride group), 150.63 (ACP-CPP), 155.51 (fluoride + ACP-CPP) and 143.75 (control group) [Table 2]. It indicates that there is no increase in micro hardness at the enamel subsurface, which is not in accordance with the previous studies. There is no remineralization at subsurface level and all the treatment groups failed to remineralize the subsurface lesion in depth. Nevertheless, fluoride, fluoride + ACP-CPP and to a lesser extent ACP-CPP can remineralize the surface lesion. There was no increase in CSMH at the subsurface level and the values suggested that, that none of the surface treatment agents could penetrate the demineralized enamel at the subsurface level. The reason could be; fluoride ions and ACP-CPP were not able to penetrate the subsurface enamel area, the *in vitro* set up is not exactly mimicking the *in vivo* conditions occurring in the mouth, duration of the experimental set up (seven days) is too short.

Conclusions

Within the limits, the present study concludes that; Fluoride varnish is effective in remineralizing the early enamel caries at the surface level. ACP-CPP cream is effective, but to a lesser extent than fluoride varnish in remineralizing early enamel caries at surface level. Combination of fluoride varnish and ACP-CPP does not provide any additive remineralization potential when compared to fluoride varnish alone at the surface level. Fluoride varnish, ACP-CPP cream and combination of fluoride varnish and ACP-CPP are not effective in remineralizing the early enamel caries at the subsurface level. However, one must bear in mind that remineralization *in vitro* may be quite different when compared to dynamic complex biological system which usually occurs in oral cavity *in vivo*. Thus, direct extrapolations to clinical conditions must be exercised with caution because of obvious limitations of *in vitro* studies.

Acknowledgment

I am extremely thankful to Dr. P.R. Harikrishna Varma, Scientist in charge and Dr. Manoj Komath, Scientist, Bio Ceramics Laboratory, BMT Wing, Sri Chithra Thirunal Institute of Medical Sciences and Technology, Thiruvananthapuram, for their valuable interactions and suggestions. I wish to put on record my gratitude to them for providing the Vickers hardness testing machine for this study and extending the laboratory facilities.

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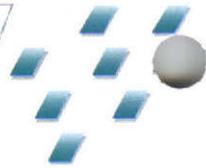
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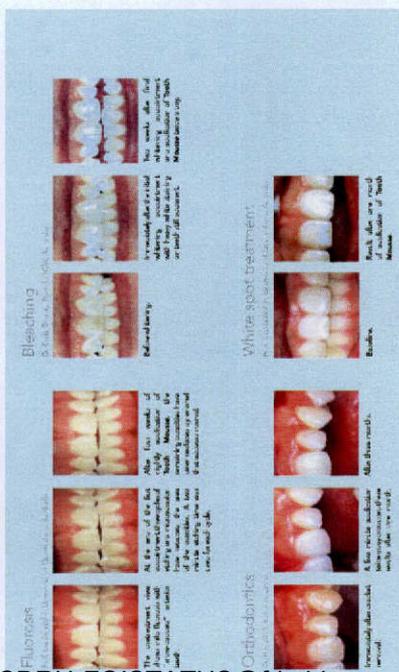
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Tooth Mouse and MI Paste Plus from GC.

Remineralising protective creates
with triple the benefit:
Strengthen. Protect. Replenish.

A healthy balance in the mouth inhibits demineralisation of dental and enamel and rebalances mineralisation.



'GC'

A winning combination for a smile that lasts a lifetime.

Just as your body needs to be conditioned to stay and look healthy, your teeth need conditioning too. Over time, teeth can lose nutrients and strength as a result of whitening procedures, highly acidic food or drinks and the natural aging process. It's important to protect and revitalize teeth to keep them looking terrific for a lifetime. GC presents two breakthrough dental treatment products to do just that.

Tooth Mousse and MI Paste Plus

- For remineralizing ... and inhibiting initial caries lesions
- For desensitizing^{1,2}
- During and after orthodontic treatment, especially on white spots³
- For providing extra protection, especially against acid attacks^{4,5}
- For pregnant women

Remineralisation

Hypermineralisation

After using MI Paste Plus and Tooth Mousse, the remineralisation process is enhanced, resulting in a thicker, more resilient enamel layer that is more resistant to acid attacks.

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The first natural system for protection.

Introduced in 2002, Tooth Mousse remains an excellent choice in fending off acid attacks. As well as buffering the acidity and restoring the mouth's proper mineral balance in just a few minutes, Tooth Mousse remineralises enamel lesions due to the high level of calcium and phosphate it provides. Tooth Mousse is the ideal way to give your patients maximum all-around protection. Thanks to RECALDENT™ - its revolutionary ingredient!

RECALDENT™ is derived from casein, the milk protein. Recent research has shown that milk's protective demineralisation and, even better, remineralisation effect lies in a part of the casein protein called casein phosphopeptide (CPP), which carries calcium and phosphate ions as Amorphous Calcium Phosphate (ACP). Calcium phosphate is usually insoluble in other words, it forms a crystalline structure at neutral pH. However, the CPP keeps the calcium and phosphate in an amorphous, non-crystalline state, much like the saliva's mineral components. This means that the CPP-ACP complex, or RECALDENT™, is the optimal way to deliver calcium and phosphate ions to the surface of the tooth and within dental plaque. In short, RECALDENT™ depresses enamel demineralisation and, even better, remineralises enamel.



The benefits of Tooth Mousse at a glance:

- Supports greater resistance to acid attacks^{6,7} by inhibiting enamel demineralisation^{8,9} and inducing remineralisation at the tooth surface and sub-surface
- Reduces hypersensitivity by obturating open dentinal tubules^{10,11}
- Prevents initial caries forming thanks to its anti-cariogenic properties¹²
- Reverses the white spot lesions process, even after orthodontic treatment¹³



GC has taken this sensational idea and made it even better. With MI Paste Plus.

MI Paste Plus has all the benefits and great taste of Tooth Mousse. What's more, it optimises both fluoride delivery to enamel and fluoride intake. And thanks to a unique, patented form of fluoride, MI Paste Plus combines remineralisation and fluoridation. MI Paste Plus contains 900 parts per million (ppm) fluoride ions. While those ions are well known for remineralising enamel, MI Paste Plus with CPP-ACP is the only product that delivers the ideal calcium, phosphate and fluoride ratio of 5:3:1. MI Paste Plus with ACPF releases all three of the ions needed to form acid-resistant fluorapatite by both remineralisation and fluoridation.¹⁴

Combining remineralisation and fluoridation. The benefits of MI Paste Plus at a glance:

- Buffers the pH changes in plaque
- Impairs the adhesion and growth of Streptococcus mutans and Streptococcus sobrinus to the tooth surface¹⁵
- Remineralises enamel lesions (remineralisation)¹⁶ and makes remineralised enamel more resistant to acid attacks¹⁷
- Optimises the way fluoride is transported to enamel and the fluoride intake by enamel¹⁸

How to apply Tooth Mousse and MI Paste Plus

Tooth Mousse and MI Paste Plus are applied topically to at-risk surfaces. First clean the teeth. Then sneeze a small amount of product across tooth surfaces with a clean finger or cotton-tipped applicator and let it work for three to five minutes. Do not rinse off. For at-home use when your patients apply Tooth Mousse and MI Paste Plus immediately before going to bed, they should leave it on their teeth to slowly dissolve overnight.



Note: MI Paste Plus, Tooth Mousse and MI Paste Plus are trademarks of the brand, with a return-free policy.

MI Paste™ & MI Paste Plus™				
About	Indications	How to Apply	FAQs	Testimonials

Frequently Asked Questions

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A

Why has it taken so long for ACP to enter the market?

If calcium phosphate is such hot stuff, why has it taken so long to find its way into dental products? It's not as simple as dabbing minerals straight onto teeth, Dr. Tung explains, because in solid form they won't bind to the teeth. Instead, he has worked with a compound called amorphous calcium phosphate (ACP) which, when combined with water, crystallizes onto the teeth in the form of new enamel.

The Australian team, led by Eric C. Reynolds, AO, head of the school of dental science at the University of Melbourne, Australia, took a different approach to ACP. They noticed that milk products seemed to have beneficial effects on tooth enamel and realized that casein phosphopeptides (CPP) could stabilize the molecules until they are applied to teeth, and help bind them to plaque, bacteria, soft tissue, and dentin where they are slowly released to form enamel. The Australians have licensed their formula for CPP-ACP to GC America, which sells it as MI Paste in the United States and Canada and Tooth Mousse elsewhere.

Does MI Paste have the ADA Seal of Acceptance? What is the ADA Seal of Acceptance Program?

The ADA decided not to utilize the seal program for prescription products after January 1, 2008. The ADA instituted the *Professional Product Review (PPR)* in place of the seal program for this category. The PPR is provided free to ADA members (and by subscription to others) four times a year and includes comparative evaluations of a number of products in a category with usually three product categories per issue. The ADA concurrently made the decision to **concentrate on the PPR and to eliminate the Seal Program for professional and prescription products.** Consequently, professional and

prescription products are no longer eligible for the ADA Seal of Acceptance.

However, the **Seal Program for consumer products remains in place** to continue to help consumers make informed consumer product decisions. When consumers see the ADA Seal on a product, they can be assured that it has undergone a rigorous objective, scientific review of its safety and effectiveness. The Seal on product labeling means that the product says what it does and does what it says. Although it is strictly voluntary, more than 100 companies participate in the Seal program. **Participating companies commit significant resources** to test and market products in the Seal program. More than 400 dental products that are sold to consumers carry the Seal of Acceptance. These include toothpaste, dental floss, manual and electric toothbrushes, mouth rinse and chewing gum.

[ADA Seal page](#)
List of ADA Seal of Acceptance for consumer products.

How to apply MI Paste PLUS?

Just like MI Paste, MI Paste PLUS is applied topically to at-risk surfaces. This can be done by first cleaning the teeth and then smearing a small amount of MI Paste PLUS across the tooth surfaces with a clean finger or cotton-tipped applicator.

When applied immediately before bed, the material is then left in place, to dissolve slowly overnight. It is not rinsed out. MI Paste PLUS can also be applied topically to the teeth using a custom-made tray such as a pull-down tray made for applying a whitening gel.

- Apply using a clean finger or custom tray
- Leave undisturbed for a minimum of three minutes
- Spread around the mouth and teeth with the tongue and hold for one to two minutes
- Expectorate, do not rinse and avoid food or drink for 30 minutes
- How often to apply?
 - Nightly application is the standard recommendation
 - For high risk patients, apply both morning and night

B

Will MI Paste alleviate sensitivity from bruxism?

The occlusion or bite is causing the sensitivity and until that is corrected MI paste will not eliminate the sensitivity. The sensitivity is due to the occlusion and the clenching and unfortunately MI Paste would probably not alleviate the sensitivity.

Can you brush on MI Paste?

MI Paste should be applied with cotton swab, gloved or clean finger or with a custom tray. Brushing is not recommended to applying MI Paste.

How soon after I brush do I apply MI Paste?

After brushing with an over the counter toothpaste (1,000 ppm fluoride) immediately apply a pea-size amount of MI Paste to the tooth surfaces using either a clean finger or a cotton swab.

Does MI Paste/MI Paste PLUS contain Bis-Phenol A (BPA)?

Considering the recent inquiries we would like to confirm that GC dental products sold in the United States of America, Canada or Latin America do not contain Bis-Phenol A (BPA) as an ingredient. Also GCA does not import any products into the United States of America, Canada or Lat America containing Bis-GMA.

C

Is MI Paste PLUS safe to use on children?

Because MI Paste PLUS contains a level of fluoride similar to that of adult strength toothpastes, there are issues when the material is ingested either accidentally or deliberately in children because of their low birth weight. Ingestion of a pea-size amount (0.5mL) of MI Paste PLUS will contribute 0.45mg of fluoride ion to the daily fluoride intake.

In young children (up to six years of age), use of MI Paste PLUS is contra indicated because it may increase the risk of dental fluorosis. Children aged six years and above can use both standard (adult strength) toothpaste (1000ppm) and MI Paste PLUS without an increased risk of dental fluorosis.

CAUTION

- MI Paste PLUS contains 0.2% (900ppm) fluoride. It is not recommend for children under six.
- it is not recommended for overnight application in children under 12.

- Do not use on patients with a milk protein allergy (caesin IgE) and/or sensitivity to benzoate preservatives

Why is calcium so important?

It is critical to sustain the bio-available calcium ion level within the saliva, to remineralize the tooth structure before attempting to restore it. Using fluoride products alone is insufficient to cause remineralization or prevent severe demineralization from occurring, because the critical pH of enamel relates strongly to the calcium concentration in the saliva and the plaque fluid. To maintain as high a level of calcium in the plaque fluid as possible, apply MI Paste PLUS each morning and again each night, immediately before retiring. This contains and releases calcium, phosphate and fluoride ions in the correct ratio (5:3:1) for optimal remineralization of tooth structure.

If a patient is a high caries risk, a home program may continue to include high fluoride concentration toothpaste or gel on an intermittent basis to suppress plaque levels and suppress plaque fermentation. Use a detergent-free normal strength toothpaste morning and night, but a high strength (5000 ppm) fluoride toothpaste or gel (9000 ppm) in the middle of the day, in order to exert antibacterial effects, and to prevent potential problems with sequestering calcium ions.

Why not to use antimicrobial rinse such as chlorhexidine gluconate within 2 hours of using fluoride toothpaste containing sodium lauryl sulfate?

It is suggested not to use antimicrobial rinses, such as chlorhexidine gluconate (CHA) or cetylpyridinium chloride (CPC) within 2 hours of fluoride toothpaste containing sodium lauryl sulfate because the sodium lauryl sulphate saponification component in dentifrice can reduce chlorhexidine activity..

What is Cetylpyridinium Chloride (CPC)

CPC is a cationic quaternary ammonium compound in some types of mouthwashes, toothpastes, lozenges, throat sprays, anti-snore throat sprays, breath sprays, and nasal sprays. It is an antiseptic that kills bacteria and other microorganisms. It has been shown to be effective in preventing dental plaque and reducing gingivitis. It has also been used as an ingredient in certain pesticides. This ingredient has also been shown to cause brown stains between the teeth.

CPC has a positive cationic (Sodium Laurel Sulfate is negative) resulting in negating the desired effect.

Crest Pro-Health Rinse contains CPC, how does it work?

Crest Pro-health Rinse contains a clinically proven bactericidal agent, CPC that's attracted to bacteria in the mouth. CPC interacts with the bacterial membrane and weakens it. The cellular pressure disrupts the cell membrane and kills the bacteria.

What is the protocol with Chlorhexidine Gluconate and MI Paste?

It is suggested to wait 2 - 3 hours after rinsing with antimicrobial rinses, such as chlorhexidine gluconate (CHX) or cetylpyridinium chloride (CPC) before applying MI Paste. Chlorhexidine gluconate adheres to the tooth surface just as MI Paste, so it is best to wait 2 - 3 hours before applying MI Paste after rinsing with CHX.

What goes first? How long should a patient wait between applying Chlorhexidine Gluconate (CHX) and MI Paste and will they affect each others efficiency?

It is best to wait 2-3 hours after rinsing and applying MI Paste. As to which goes first the order is not the important factor just that there is sufficient time between applications.

How young can a child be to apply MI Paste?

MI Paste is a safe product to use for babies' teeth and is well tolerated by children and tastes delicious. MI Paste is especially useful for children under 2 years of age, where toxicological issues mean normal or high strength fluoride products are contraindicated.

MI Paste is a safe product to use for babies' teeth and is well tolerated by children and tastes delicious. RECALDENT™ (CPP-ACP) is derived from the milk protein casein called casein phosphopeptide. Do not use on patients with the milk protein casein allergy.

Newly erupted teeth have yet to complete their enamel maturation and until this occurs they are more vulnerable to an acid attack. Boosting levels of calcium and phosphate in the saliva facilitates the normal post-eruption maturation process and replaces any mineral lost on a daily basis. RECALDENT™ (CPP-ACP) is derived from cow's milk and is ideal for protecting deciduous teeth at a time when oral care is difficult.

MI Paste is applied to the teeth twice daily with a clean finger to provide a surface film that will raise levels of essential minerals (calcium and phosphate), as well as inhibit the growth of caries causing bacteria.

At what age can children use MI Paste PLUS?

MI Paste *PLUS*, which contains 900 ppm fluoride ions (0.2% sodium fluoride), is not recommended for children under six years of age.

Is there an increase in supra-gingival calculus associated with the use of MI Paste?

Casein Phosphopeptides (CPP) inhibits the transformation of amorphous calcium phosphate into crystalline phases (Holt and van Kemenade, 1989) such that they should not directly promote calculus formation but instead provide a plaque reservoir of soluble calcium phosphate ions capable of diffusing into subsurface enamel and promoting remineralization.

How much calcium is in MI paste?

The amount of calcium contained in MI paste is 13mg/g.

Canker sores and MI Paste

Canker sores are shallow, painful sores in the mouth. They are usually red or may sometimes have a white coating over them. You might get them on the inside of your lips, the insides of your cheeks, the base of your gums or under your tongue. Anyone can get canker sores, but women and people in their teens and 20s get them more often. Canker sores may run in families, but they aren't contagious. Doctors don't know what causes canker sores, but they may be triggered by stress, poor nutrition, food allergies and menstrual periods. The acid from strawberries and tomatoes may also be a contributing factor.

MI Paste/MI Paste *PLUS* does not have any history of causing canker sores. Hydroxybenzoate, often called paraben and is widely used as a preservative in the cosmetic and pharmaceutical industries, such as shampoos, lotions, toothpaste, etc. It is also used as a food additive. Parabens are considered to be safe, but can cause skin irritation or dermatitis on some individuals with paraben allergies.

With that in mind, that is why the caution statement is posted on the box: "RECALDENT™ is derived from milk casein. Do not use on patients with a milk protein and/or hydroxybenzoate allergy."

It is suggested that the patient temporarily stop using MI Paste/MI Paste *PLUS* until the canker sores have healed. Once the canker sores have healed, the patient may want to resume applying MI Paste *PLUS*. As mentioned above, it could be caused from stress, nutrition or food allergies, not relating to MI Paste *PLUS*. It is always wise to check with a physician or dentist.

D

Why not use MI Paste/MI Paste PLUS as a dentifrice?

The reason why you wouldn't want to use it as a dentifrice is because it is "sticky" which gives it the substantivity. Having the milk protein in it, with most toothbrushes, more of it will stick to the bristles of the brush than when you use the tray or finger technique.

The patient would be wasting too much product in the bristles of the toothbrush and not on the tooth surfaces. We want the patient to get the most use out of her tube of MI Paste. Also, most people rinse after brushing and again this would defeat the benefit of MI Paste.

I am not a dentist, my dentist prescribed MI Paste but I can't find a pharmacy that can fill the prescription, what do I do?

As a company we do not sell direct, MI Paste is only sold to the dental profession through their dental dealer. If your dentist prescribed MI Paste more than likely he will have it in his office. Your dentist can always purchase MI Paste through his local dental dealer.

Can a patient on kidney dialysis use MI Paste?

The amount of phosphate contained in MI Paste 40g tube is more than 0.2%. We say "more than" because 0.2% is phosphoric acid by itself and CPP-ACP also contains phosphate.

GCC does not recommend using MI Paste on dialysis patients, although the amount of ingestion of phosphate by using MI Paste would be very small.

We do not recommend kidney dialysis patients to use MI Paste. Although the amount of ingestion of phosphate is very small we do not recommend its use.

We do not show a warning about phosphate for dialysis patients in the IFU. Instead, we show all the ingredients on the tubes and boxes.

E

Can MI Paste be used on patients with dental erosion?

MI Paste is extremely effective at remineralizing erosion areas, and can be used in patients who have gastro esophageal reflux disease or eating disorders such as bulimia in order to protect these areas from dental erosion. If the saliva in the mouth is of good quality, as shown by saliva profiling, then fluoride is able to promote limited remineralization because calcium and phosphate is present.

However, fluoride will ineffectively remineralize teeth if the salivary flow is inadequate, because of the low levels of calcium and phosphate. MI Paste provides bio-available calcium and phosphate ions at the tooth surface at much higher levels than can be maintained by normal salivary flow. Therefore MI Paste is recommended even for patients with normal salivary flow.

F

Why add fluoride to MI Paste?

MI Paste PLUS exhibits significantly greater anti-caries properties than its fluoride content alone, it is a superior product for professional application or at-home use. CPP-ACPF (MI Paste PLUS) gives greater anti-caries effects than CPP-ACP (MI Paste), and is designed for patients at high risk for dental caries and dental erosion. Even though the pH of MI Paste PLUS is above 7.0, it enhances mineral uptake without encouraging the formation of calculus.

The mechanism of anti-cariogenicity for CPP-ACPF involves elevating levels of calcium, phosphate and fluoride ions at the tooth surface and within dental plaque, thereby depressing enamel demineralization and enhancing remineralization. The increases in supragingival plaque levels of calcium, phosphate and fluoride ions produced by CPP-ACPF are markedly greater than those obtained with 1000ppm fluoride toothpastes.

How does fluoride and CPP-ACP work?

FLUORIDE AND CPP-ACP

Four Fluoride ions promote the formation of fluorapatite in the presence of calcium ions and phosphate ions. This is now believed to be the major mechanism of fluoride ion's action in preventing tooth decay. However, fluoride ions can only promote remineralization of tooth enamel with fluorapatite if enough salivary or plaque calcium and phosphate ions are available when the fluoride is topically applied. Hence, on topical application of fluoride ions, the availability of calcium ions and phosphate ions are the limiting factor for net enamel remineralization to occur (Ten Cate, 1999). MI Paste PLUS is a superior form of fluoride ions as it also contains CPP-ACP. MI Paste PLUS therefore contains bio-available calcium ions, phosphate ions and fluoride ions. CPP-ACP plus fluoride has been shown to increase fluoride's uptake into plaque and subsurface enamel and substantially increase subsurface enamel remineralization in situ with fluorapatite relative to fluoride alone, by providing bio-available calcium ions, phosphate ions and fluoride ions in the correct molar ratio to form fluorapatite.

How much fluoride is in MI Paste PLUS?

MI Paste PLUS contains 900 parts per million (ppm) fluoride ions a level just below that found in normal adult-strength toothpastes (1000ppm). While the remineralizing actions of the fluoride ions are well known, MI Paste PLUS with ACPF releases fluoride as well as calcium and phosphate ions, thereby providing all the three ions which are required for formation of acid-resistant fluorapatite. This level of fluoride also exerts some effects on the utilization of sugars as an energy source by dental plaque bacteria, which reduces their overall contribution to plaque fermentation.

How is fructose metabolized?

It is desirable to minimize patients' high frequency consumption of fermentable dietary substrates, including those in foods, drinks, and medications. Nonfermentable dietary sweeteners are recommended whenever possible, such as xylitol, sorbitol, aspartame or saccharin. The polyols such as xylitol are anticariogenic as they result in decrease acid fermentation by S. Mutans.

Fructose is a monosaccharide, or single sugar, that has the same chemical formula as glucose but a different molecular structure. Sometimes called fruit sugar, fructose is found in fruit, some vegetables, honey, and other plants. Fructose and other sugars are carbohydrates, an important source of energy for the body.

Does MI Paste/MI Paste PLUS have FDA 510K Clearance?

MI Paste received FDA 510K Clearance to sell and market MI Paste on October 20, 2004 (KO42200). MI Paste PLUS received FDA 510K Clearance on April 12 2007 (KO70854). Both MI Paste and MI Paste PLUS have FDA 510K Clearance as a prophylactic paste and for treating hypersensitivity.

MI Paste is cleared in Canada by Health Canada, MI Paste PLUS is pending.

Recommended Indications:

To be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment. Secondly, MI Paste/MI Paste PLUS can be used for the management of tooth sensitivity, post scaling, root planing and bleaching.

Note the FDA does not give approvals but clearance based on the data submitted.

510K Clearance

MI Paste - K042200
MI Paste PLUS - K070854

Is MI Paste/MI Paste PLUS approved by the FDA?

Yes GC America received clearance to sell and market MI Paste on Oct. 20, 2004, K042200
MI Paste PLUS received clearance to sell and market on April 12, 2004, K070854
MI Paste is cleared in Canada by Health Canada, MI Paste PLUS is pending

Why does MI Paste only come in mixed flavors when most patients prefer mint?

MI Paste is only available in an assorted pack (melon, mint, vanilla, strawberry and tutti-frutti). MI Paste PLUS is available in an assorted pack and in a mint only 10-pack.

A patient is allergic to strawberries, can they use MI Paste strawberry flavor? I know the flavor comes from artificial flavoring, but I am not sure if real fruit is used at any point.

MI Paste's flavoring agent is artificial. No real fruit is used in the flavoring process.

Is fluoride necessary for enamel to uptake calcium and phosphate ions?

Fluoride is beneficial but not necessary for the calcium and phosphate ion to be beneficial to the tooth substrate.

Is it okay to rinse with fluoride prior to using MI Paste instead of fluoride toothpaste?

Brushing with 900/1000 ppm toothpaste is acceptable and than apply MI Paste. If using a high strength toothpaste (5000 ppm or more) it is suggested to wait at least 2 hours before applying MI Paste. The same goes for rinsing with a high fluoride rinse.

Is toothpaste or fluoride rinse to be rinsed after use or just spit out to maximize the amount of fluoride available?

Brush your teeth with your regular toothpaste 900 ppm, including spitting and rinse the mouth, than apply MI Paste.

What type of fluoride is better to combine with MI Paste, stannous or sodium fluoride?

One fluoride is not better than the other. Stannous fluoride has a tendency to stain, which is why sodium fluoride is more popular. Do not combine, separate applications especially if using a high fluoride product like Prevident. A suggestion, have the patient use the high fluoride in the AM and MI Paste in the PM. Again with the high dose you want to separate treatment, you may want to wait 2 - 3 hours.

Should MI Paste be used after every fluoride treatment?

Yes, studies at the University of Melbourne have demonstrated that RECALDENT™ CPP-ACP significantly increased the uptake of fluoride into the tooth enamel creating fluorapatite that is more resistant to acid challenge. Thus MI Paste is recommended for treatment of patients of both high and low caries risk.

In terms of a patient who has a low caries risk, a six monthly application of neutral sodium fluoride gel followed by MI Paste is recommended.

In patients who use no fluoride products, RECALDENT™ CPP-ACP will still be effective, since in all patients there are halo effects of fluoride in the water and in their diet. CPP-ACP is able to remineralize tooth structure in the complete absence of fluoride, and this is through the formation of hydroxyapatite.

Is MI Paste an alternative to fluoride for anti-fluoride patients?

Yes. The fact that MI Paste is derived from the milk protein, casein, it is completely natural and safe and therefore is often an effective preventive treatment for patients who are anti-fluoride.

G

Grinding, Sensitivity and MI Paste

Please talk with your dental professional about grinding and what can be done to help alleviate the discomfort. MI Paste can be used for patients with aggressive tooth wear, where the tooth surfaces have become sensitive. Please keep in mind, MI Paste will not replace the enamel you wore down. MI Paste will help to remineralize the enamel you have left and help to reduce sensitivity.

Does MI Paste or MI Paste PLUS contain Gluten?

We confirm that MI Paste/MI Paste PLUS does not contain gluten. It contains nothing other than the ingredients listed on the tube and box.

Why is propylene glycol in MI Paste/MI Paste PLUS?

Propylene glycol is used in oral pastes as a thickening agent. It is digestible and the body turns it into lactic acid. Propylene glycol is safe and is listed by the FDA as GRAS (generally regarded as safe.) Diethylene glycol is toxic.

H

With so many other options available for dental hypersensitivity, why MI Paste?

When MI Paste with RECALDENT™ (CPP-ACP) is applied onto the surface of dentin, the protein component bonds strongly and subsequently mineral plugs form, which begin to block the tubules. Several clinical studies have shown that MI Paste has a potent long acting desensitizing effect when used in patients with cervical sensitive dentin.

MI Paste with RECALDENT™ (CPP-ACP) applied at least once daily provides both immediate and long term solutions to the common problem of dental hypersensitivity. It can arrest the process of dental erosion, which is a common underlying cause of chronic tooth sensitivity.

What is a hydroxybenzoate allergy?

What sort of products contain hydroxybenzoate?

How would someone know if they are allergic to hydroxybenzoate?

Is hydroxybenzoate in food, sunscreen?

Is hydroxybenzoate a preservative?

Para-hydroxybenzoate is often called as Paraben and is widely used as preservatives in the cosmetic and pharmaceutical industries, such as shampoos, lotions, toothpaste etc. They are also used as food additives. Parabens are considered to be safe, but can cause skin irritation or dermatitis on some individuals with paraben allergies.

Should a patient consider incorporating MI Paste into their daily dental homecare?

The MI Paste protocols are intended for moderate to high risk patients. However, keep in mind that demineralization/remineralization is occurring continuously in the mouth. Once you have reversed the negative effects of demineralization you will need to maintain a healthy oral cavity. If a patient has experienced demineralization problems in the past, the patient can only benefit from incorporating MI Paste into their daily dental routine. Just as we have continuous exposure to fluoride we need the continuous exposure of calcium and phosphate in MI Paste.

K

Kidney Disease - MI Paste/Dialysis Patient

MI Paste protocol sheet, it says you should "Contact a physician if recommending MI Paste for a renal dialysis patient." Why is this?

People with kidney disease are susceptible to an imbalance of phosphorus and calcium. During normal renal function the body is in homeostasis; however, during kidney disease the body is not able to remove phosphorus well. Phosphorus builds up in the blood and sends a signal to the parathyroid glands to emit parathyroid hormone which triggers an increase in calcium within the blood. The best source of calcium is in the bones; therefore, the bones can become less dense (thinning of the lamina dura and pulp chamber are often observed in the dialysis patient). At this point we have a lot of phosphorus in the blood - which puts the patient at high risk for heart attack. Also, we have a lot of calcium in the blood - this condition is known as secondary hyperparathyroidism or Renal Osteodystrophy. The excess calcium can be deposited into blood vessels, heart, lungs, liver, and other soft tissues. Calcium can get so high that it causes Calcinosis a very serious condition. Obviously, adding more phosphorus or calcium to the diet to a dialysis patient can be a problem (even a considerably small amount). MI Paste has phosphorus and calcium in it.

Of course, since it is only used topically, that raises some questions - how much would be ok or how much would be lethal (or damaging). The answer to this, simply, is every patient is different and each patient could vary from day to day or week to week (they're monitored weekly or monthly, dependant on their needs/stability). Consulting with the renal specialist can be confusing because there are 5 stages of kidney disease and the phosphorus/calcium thing is more important in some stages than others. With that said, understanding the disease process of the population will help you when discussing the patients needs when communicating with the nephrologist, renal nurse, or renal dietitian. Remember, if approved by the medical team, the issue can be the helped by recommending the use of MI Paste correctly by using a small amount. If you spit out the excess you will likely be in good shape. GC America is trying to be cautious and make people aware and that's always a good thing.

The salivary chemistry of renal patients does not favor caries infections so that's something to consider too. If you do a saliva test and it comes back buffering off the charts and a very high pH caries may be off the worry list. However, you are now aware that MI Paste is not only of value for caries but a list of other conditions; therefore, you'll still may want to consider the use MI Paste for palliative care of the intense xerostomia dialysis patients have (etc.).

Comments provided by:

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L

Does MI Paste contain lactose?

MI Paste/MI Paste *PLUS* contains RECALDENT™ (CPP-ACP), it is milk derived with lactose content less than 0.01%. The amount is very small.

M

Does MI Paste/MI Paste *PLUS* have melamin, do they use milk from China to create MI Paste?

The milk used to create RECALDENT™ CPP-ACP comes from the dairy cows of New Zealand. The milk does not originate from China. We appreciate your concern for safety and assure you that MI Paste/MI Paste *PLUS* does not contain melamine.

When To Use MI Paste *PLUS* Rather Than MI Paste?

MI Paste *PLUS* is recommended at night for patients with marked salivary dysfunction (dry mouth), for example, because of medications, systemic illnesses, or salivary gland disease, because of the enhanced risk of mineral loss from dental caries or dental erosion. These patients would also benefit from daytime applications of GC Dry Mouth Gel to gain symptomatic relief from oral dryness. Patients should be at least six years of age before using MI Paste *PLUS*.

Regular MI Paste, which is fluoride-free, is the appropriate product to use in infants and young children (up to six years of age) because of issues with fluoride ingestion.

- Patients with active caries
- Patients with poor plaque control
- Patients with erosion and gastric reflux
- Xerostomic patients
- Patients with an acidic oral environment
- Medically compromised patients
- Desensitizing

- White spot lesion
- Pregnant mothers
- Orthodontic treatment (during and after)
- High caries risk patients
- Extra protection for teeth

Is MI Paste/MI Paste PLUS safe for patients with milk allergies?

The active ingredient in MI Paste/MI Paste PLUS is RECALDENT™ (CPP-ACP). RECALDENT™ (CPP-ACP) is milk derived and should not be used by patients with milk protein allergies. Casein phosphopeptides are derived from milk casein. Do not use MI Paste/MI Paste PLUS if you have a proven or suspected milk protein (IgE) allergy.

What separates MI Paste from other calcium products?

RECALDENT™ (CPP-ACP) technology has been extensively researched at the University of Melbourne Dental School (Australia) since the 1980's. There are over 100 studies substantiating the benefits of RECALDENT™ (CPP-ACP), the active ingredient in MI Paste.

What is MI Paste PLUS?

MI Paste PLUS contains a unique, patented form of fluoride in a product designed for high-risk patients. It has all the benefits of MI Paste with enhanced remineralizing capabilities.

MI Paste PLUS provides a superior form of fluoride ions as it also contains CPP-ACP (casein phosphopeptide-amorphous calcium phosphate). CPP-ACP + fluoride (F) has been shown to increase fluoride's uptake into plaque and subsurface enamel and substantially increase subsurface enamel remineralization in situ with fluorapatite relative to fluoride alone, by providing bio-available calcium, phosphate and fluoride ions in the correct molar ratio to form fluorapatite in the body of the lesion, not just at the surface layer. CPP-ACPF (MI Paste PLUS) gives greater anti-caries effects than CPP-ACP (MI Paste) and is designed for patients at high risk for dental caries and dental erosion.

For children under six years of age, the use of the regular MI Paste is recommended to provide the protection required.

Why MI Paste PLUS with fluoride vs Prevident booster?

MI Paste with RECALDENT™ (CPP-ACP) combined with a low dose fluoride applied regularly aids for thorough remineralization. Thorough remineralization extends to the depth of the enamel rod, versus superficial remineralization which may extend partially in depth.

O

Is one application of MI Paste beneficial?

Yes, particularly after and/or with a professional fluoride application because MI Paste with RECALDENT™ (CPP-ACP) promotes the uptake of fluoride ion by tooth enamel. MI Paste may also be used for a patient who has a sensitivity problem. MI Paste could be used as a single application for a patient who had cervical dentinal hypersensitivity where most of the issues of lifestyle were comfortably addressed at that same visit. If one had concerns about compliance, then the patient could be given MI Paste to take home with them.

An orthodontic patient wants whitening however, the patient has decalcification on the anterior teeth, is it best to bleach first or use MI Paste initially?

For some white spot lesions it may be necessary to first pre-treat the lesion before application of MI Paste. This pre-treatment may involve bleaching, acid etching or microabrasion. Recent research at the Dental School at the University of Melbourne has demonstrated that pre-bleaching is an effective pre-treatment for MI Paste application.

P

Why is there no patient instruction in the box?

How to use MI Paste/MI Paste *PLUS* is dependent upon why and how the dental professional recommends it application. It is a case by case situation. Ask your dental professional for clarification on frequency and method/of application.

What About Pregnant Mothers?

There are no proven dental or general health benefits or risks from pre-natal fluoride containing products. Fluoride supplements are not indicated in pregnancy, however MI Paste *PLUS* can be used as a topical treatment in high caries risk pregnant women or in situations where reflux is causing dental erosion and dentinal hypersensitivity

What is the pH of MI Paste

The pH of MI Paste is 7.8. it is considered a neutral pH based on a range of 0 – 14 scale. 11/13/2008

What purpose is the phosphoric acid serving? How much is in there and will it have any effect in demineralizing enamel?

The purpose of the phosphoric acid is to buffer the CPP-ACP. MI Paste is an exceptionally good buffer of acid yet we still need the formulation to be relatively neutral to be able to get the most effective levels of remineralization. The final pH of MI Paste is around 7.8 (slightly alkaline), without the phosphoric acid it would be higher (more alkaline) which is helpful for buffering an acidic mouth but not as effective for the remineralization process.

Phosphoric acid is used to adjust the pH of MI Paste to get it close to neutral instead of alkaline (basic).

The percentage composition of phosphoric acid is < 00.3% (ie less than .3 of one percent) so it is very small. You can imagine it is more added as a formulation "tweak" to ensure the optimum performance (phosphoric acid is a recognized food additive and antioxidant) balancing between buffering and remineralization benefits. There is absolutely zero chance/potential for demineralization.

Is MI Paste safe to use while pregnant?

Regular use of MI Paste during pregnancy helps to maintain elevated levels of calcium and phosphate in the saliva, protecting the teeth from dental erosion. There is also an additional benefit because MI Paste will inhibit the growth and adhesion of mutans streptococci, which would otherwise flourish in an acidic oral environment. Any MI Paste material that is swallowed is completely safe, and will contribute towards dietary calcium.

Is MI Paste available by prescription or is only distributed through dental offices?

MI Paste is only available through the dental profession. It is available through the dental office, it is not a prescription item.

What is pH?

pH is the measurement of the hydrogen ion concentration, [H+]. This value ranges from 0 to 14 pH. Values below 7 pH exhibit acidic properties. Values above 7 pH exhibit basic (also known as caustic or alkaline) properties. Since 7 pH is the center of the measurement scale, it is neither acidic nor basic and is, therefore, called "neutral."

One way to measure pH is by indicators, materials that are specifically designed to change color when exposed to different pH values. The color of a wetted sample paper is matched to a color on a color chart to infer a pH value. pH paper is available for narrow pH ranges (for example, 3.0 to 5.5 pH, 4.5 to 7.5 pH and 6.0 to 8.0 pH), and fairly wide pH ranges of 1.0 to 11.0 pH.

R

What is the active ingredient in MI Paste?

The active ingredient in MI Paste, RECALDENT™ (CPP-ACP) is milk derived. RECALDENT™ (CPP-ACP) is a complex of casein phosphopeptides (CPP) and amorphous calcium phosphate (ACP). Calcium phosphate is highly insoluble, however the peptides are able to maintain the calcium and phosphate in an ionic form, preventing the formation of insoluble calcium phosphate and therefore enabling calcium and phosphate ions to enter the tooth matrix and remineralize areas of hypomineralized enamel. Furthermore, the peptides bind to the surface of the tooth, and to the bacteria surrounding the tooth, presenting a reservoir of ionic calcium and phosphate at the tooth surface.

Root Surface caries and MI Paste

In patients with a high rate of root surface caries, a twice daily application of MI Paste helps to address the underlying problem of poor salivary parameters and prevent caries from effecting the remaining structure of the teeth. MI Paste is essential for long-term stability of the exposed root surfaces. Home care would include the application of MI Paste twice daily at a minimum.

It is critical to sustain the bio-available calcium ion level within the saliva, to remineralize the tooth structure including root surfaces. The pH of saliva relates strongly to the calcium concentration of the saliva and the plaque fluid. To maintain a high level of calcium in the plaque fluid, apply MI Paste morning and evening, immediately before retiring. The MI Paste PLUS releases calcium, phosphate and fluoride for optimal remineralization of the tooth structure including root surfaces.

MI Paste is a valuable armamentarium for patients with exposed root surfaces and caries. Your patient will benefit using MI Paste.

Radiation Treatment for cancer patient?

A patient with throat cancer who has been using MI Paste. The Radiation / Oncology Department is questioning the use of MI Paste due to the Titanium and Zinc Oxides. Will this cause "Radiation Scatter" and allow radiation to scatter to areas not aimed or patterned for radiation. Much like what deodorant does with Mammography's and/or X-Rays.

S

Would MI Paste be beneficial to patients with Sjogren's syndrome?

The combination of a reduced salivary flow and ocular dryness may indicate Sjogren's syndrome. A patient with Sjogren's syndrome would benefit from MI Paste *PLUS*. The suggested home care program would include MI Paste twice daily. Others aids include a saliva substitute, for comfort, (GC Dry Mouth Gel by GC America) and intermittent chlorhexidine therapy and/or fluoride treatment to suppress harmful bacterial. Always check with your dental professional.

Are there any SALICYLATES in MI Paste? Are there any natural or artificial salicylates in any of the flavorings, CPP-ACP, CMC-Na and Xylitol.

Salicylates are a naturally occurring group of chemicals found in a wide range of foods, herbs and spices. Salicylates are similar in structure to salicylic acid which is manufactured to produce aspirin. Some people may be sensitive or allergic to aspirin and also react to foods containing salicylates.

Fruit containing salicylates include: Apricot, avocado, blackberry, black currant, blueberry, boysenberry, cherry, cranberry, currant (dried), date, grape, grapefruit, guava, Jonathan apple, kiwi fruit, lychee, mandarin, mulberry, nectarine, orange, passionfruit, peach, pineapple, plum, prune, raisin (dried), raspberry, red currant, rockmelon, strawberry, suitana (dried), watermelon etc. Food intolerance is a general term used to describe an adverse reaction to certain types of foods. Intolerance to salicylates is a relatively common condition which can be managed by avoiding foods which contain these substances. The main food sources of salicylates are fruits, vegetables, dried spices, tea and food flavorings. The average 'Western diet' has an estimated salicylate intake ranging from 10 to 200 mg per day.

- MI Paste is GRAS (generally regarded as safe)
- Salicylate is not added and not listed
- Flavor is the concern. Although salicylate is not listed on the flavors we are using, reviews on the public domains (<http://www.webmd.com/allergies/guide/salicylate-allergy>) indicate that salicylate is found in many flavors. Unfortunately, flavor receipts are manufactures trade secret, and GC does not have the compound profile of the flavors.
- As we do not have a specific QA assay for salicylates in MI Paste, we are not in a position to state the product is salicylate-free, or its level is safe to a specific patient.

Sensitivity during the prophylaxis and the benefits of applying MI Paste

Today I had one of my super sensitive Perio patients in that I numb with topical and hand scale only. Instead today I polished first with MI Paste. I usually have the patient rinse but since this patient was hypersensitive, I kept the paste on and scaled. When I got to the deeper pockets I put some paste on the tip of the scaler to help desensitize subgingivally (just like I do with the topical.) For the first time ever the patient said she had NO DISCOMFORT during the cleaning!!!! I'm so excited, yet another way to use that awesome MI Paste PLUS. It works like a charm.

-Michelle in VA

T

What time of day is best to use MI Paste?

In terms of the binding properties of MI Paste, CPP-ACP binds to oral soft tissues, to dental pellicle and also to plaque. This binding elevates the salivary levels of calcium and phosphate for extended periods. For this reason, MI Paste works best in patients when it is applied **at night before bed**, since the salivary clearance rate is low during sleep. In patients who need intensive treatment, then a **twice daily application** is sufficient in most individuals. It is recommended that MI Paste be applied immediately after flossing and brushing with a 1000 ppm fluoride toothpaste, particularly at night before bed.

RECALDENT™ CPP-ACP, the active ingredient of MI Paste, is extremely effective for desensitizing, and this is due to the combination of surface effects and its ability to remineralize hard tissues.

Some patients who have generalized cervical dentinal hypersensitivity, may also have dental erosion, and thus one needs to look carefully at their lifestyle (using particularly the resting salivary parameters) to gain insight into whether they have sub-clinical dehydration.

Why would I choose to use custom trays to administer MI Paste, when I can apply MI Paste with a clean finger and let the MI Paste sit for 3-5 minutes?

You can apply MI Paste with either a custom tray or with a clean finger. One method is not better than another. Check with your dental professional to determine what method of delivery would work best for you.

What is the purpose of adding Titanium Dioxide to MI Paste?

Titanium dioxide is used to give the white opaque look to MI Paste.

Titanium Dioxide is found in various cosmetic and dental products as well as MI Paste. It is widely used as a food additive and as a pigment in icings for baked goods, in tobacco wrappings and tobacco substitutes, in sugar syrup coatings for products sold in tablet form, and to whiten and aged cheese.

In health products, Titanium Dioxide is used in sunscreens, as a dusting powder, and in ointments and lotions. Titanium Dioxide is also used as a pigment in paints, varnishes, enamels, and lacquers to impart whiteness, opacity, and brightness; and in paper coatings and fillers to improve opacity and brightness.

V

I have a patient who is a vegan, is the calcium and phosphate in MI Paste derived from an animal source?

RECALDENT™ (CPP-ACP) is derived from the milk protein from cows.

Does MI Paste PLUS contain any ingredients that could be harmful to porcelain veneers or their bond to tooth structure?

MI Paste PLUS does not contain any ingredients that will have a negative effect on porcelain veneers or bonding. We have not received any complaints that porcelain does not bond to tooth surfaces for patients who uses MI Paste PLUS. Of course, it should not be used in the middle of bonding procedure.

How does MI Paste PLUS compare to Fluoride rinse or varnish?

Fluoride rinses contain between 200 and 900ppm fluoride, while varnishes contain between 22,600 and 25,000ppm fluoride. These can be effective preventive agents in patients with enhanced risk, but normal salivary function.

CPP-ACPF has been shown to be superior to fluoride alone in promoting fluoride uptake into plaque and enamel in people with normal salivary function. Further CPP-ACPF promotes the remineralization of subsurface enamel with fluorapatite in the body of the lesion not just at the surface layer like fluoride alone. Patients with salivary dysfunction (dry mouth) show a great propensity to mineral loss and typically lack sufficient bioavailable calcium ions for effective remineralization when fluoride is used in isolation. Using a product such as MI Paste PLUS which releases bio-available calcium as well as phosphate and fluoride ions can help to provide effective remineralization even in more challenging situations where salivary parameters are abnormally low. It boosts salivary levels of these ions in a form equally well suited to in-office professional and at-home use.

W

Can MI Paste reverse white spot lesions?

MI Paste provides the minerals (calcium and phosphate) to rebuild subsurface areas of defects in enamel, including white spot lesions from dental caries, white spot lesions associated with orthodontic treatment and fluorosis. In these defects, there are subsurface voids which can be very effectively remineralized by applying MI Paste, and this has been shown using optical and also radiographic tests at the University of Melbourne. For some white spot lesions it may be necessary to first pre-treat the lesion before application of MI Paste. This pre-treatment may involve bleaching, acid etching or microabrasion. Recent research at the Dental School at the University of Melbourne has demonstrated that pre-bleaching is an effective pre-treatment for MI Paste application.

In order to avoid the incidence of white spots, it is recommended to apply MI Paste twice daily for the entire period that brackets are in place. Immediately after the brackets are removed apply MI Paste twice daily for one month than re-evaluation the case. How fast MI Paste works will depend on the individual situation and the clinical use for which MI Paste has been chosen.

What does W/W mean on the MI Paste PLUS packaging?

w/w is an abbreviation for "by weight," used in chemistry and pharmacology to describe the concentration of a substance in a mixture or solution. Properly speaking, 2% w/w means that the mass of the substance is 2% of the total mass of the solution or mixture. The metric symbol g/g has the same meaning as w/w.

W/W stands for weight per weight. When we prepared a tube for Tooth Mousse PLUS prior to the launch in Australia, we checked the labelling of fluoride contained toothpaste available from Colgate. They stated like "Active ingredients: Sodium Fluoride 0.22% W/W". We also checked the OTC drug labelling guideline by FDA and found that they recommended to put both of percentage and ppm on the package, as ppm might be confusing for the end-users. Therefore we finally decided to put the amount both in ppm and percentage.

X

What is the amount of xylitol in MI Paste? How much MI Paste would it take to reach the therapeutic level for xylitol?

MI Paste and MI Paste PLUS both contain 2% Xylitol

Studies have shown that a therapeutic dose to reduce dental caries is 6-10 grams per day, distributed over 3-5 time periods. Most pieces of xylitol gum have about 1.5 grams each. Many products contain less than therapeutic amounts of xylitol, often

in combination with other sweeteners.

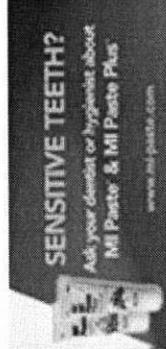
It is desirable to minimize patients' high frequency consumption of fermentable dietary substrates, including those in foods, drinks, and medications. Nonfermentable dietary sweeteners are recommended wherever possible, such as xylitol, sorbitol, aspartame, or saccharin. The polyols such as xylitol are anticariogenic, as they result in decreased acid fermentation by S. Mutans.

Why does the IFU specify Vanilla for Xerostomia?

Vanilla has the most neutral taste which we found with field evaluation and was preferred by xerostomia sufferers. In severe cases of xerostomia strong flavoring may be an irritant to already sensitive oral tissues and vanilla appears to be the least irritating.



ask dr. chiann
Let Mrs. USA help
improve your smile



Watch Amy Nieves RDH, GC America MI Specialist interview at recent dental hygiene show!



As Seen on TV

Contact Us

GC America - Professional Dental Site | View the NEW MI Paste Commercial |
Corporate Profile | Privacy Statement | As seen in the NY Daily News

'GC'



MI Paste™ & MI Paste Plus™

About

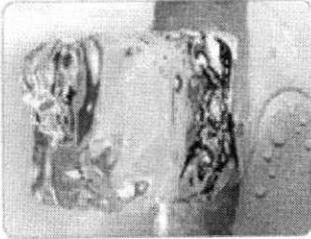
Indications

How to Apply

FAQs

Testimonials

MI Paste™ and MI Paste Plus™ Can Help Strengthen Your Teeth – No Matter Who You Are



Are your teeth sensitive to hot or cold?



Have you ever whitened your teeth?



Do you wear braces?



Have you ever had dry mouth?



Do you enjoy soft drinks?



Are you pregnant?

Indications and Contraindications

The Answer to Stronger Teeth and Better Oral Health

Numerous activities can harm your teeth and create an acid imbalance in your mouth. When that happens, your teeth can lose nutrients and strength, and you could have trouble producing enough saliva containing the minerals your teeth need to stay strong and healthy.

If you answer YES to any of the following questions, just click on it to find out how MI Paste™ and MI Paste Plus™ with RECALDENT™ (CPP-ACP) can help you.

Are your teeth sensitive?
[Do you drink soft drinks?](#)

Do you wear braces?
Do you experience dry mouth?
Do you whiten and bleach your teeth?
Are you pregnant?

MI Paste™ and MI Paste Plus™ Reduces Tooth Sensitivity

Do you like eating ice cream, but find the experience more painful than enjoyable?

You might be experiencing tooth sensitivity, which has numerous causes:

- Tooth decay
- A cracked tooth
- Worn tooth enamel
- Worn fillings and tooth roots exposed by vigorous tooth brushing
- Gum recession and disease

The Solution

MI Paste™ with RECALDENT™ (CPP-ACP) soothes sensitivity in just minutes by:

- Delivering calcium and phosphate to provide a protective covering for dental nerve endings
- Helping remineralize your teeth and restore a healthy oral mineral balance
- Buffering plaque acid as it reduces sensitivity

Available in five delicious flavors, MI Paste with RECALDENT™ (CPP-ACP) can help you strengthen, protect and condition your teeth. Ask your dentist or hygienist how it can help you enjoy a smile that lasts a lifetime.

MI Paste™ and MI Paste Plus™ Helps Fight Acid Imbalance

Soft drinks might taste good, but their acid levels can cause tooth erosion – leaving a bad taste in your mouth. In fact, there are numerous causes of harmful high oral acids, including:

- Poor oral hygiene
- Drinking excessive sodas, sports drinks and alcoholic beverages
- Pregnancy
- Gastric reflux

The Solution

MI Paste™ with RECALDENT™ (CPP-ACP) restores the acid balance by:

- Binding tooth-replenishing calcium and phosphate to teeth
- Strengthening enamel
- Buffering plaque acid
- Improving saliva flow and fluoride uptake

How acidic are some of your favorite drinks? [Learn more](#)

Available in five delicious flavors, MI Paste with RECALDENT™ (CPP-ACP) can help you strengthen, protect and condition your teeth. Ask your dentist or hygienist how it can help you enjoy a smile that lasts a lifetime.

MI Paste™ and MI Paste Plus™ Helps Prevent White Spots

Straightening your teeth with braces builds a beautiful smile, but braces can also trap food and build plaque that lead to white spots forming on your teeth.

The Solution

MI Paste™ with RECALDENT™ (CPP-ACP) delivers calcium and phosphate during orthodontia treatment to:

- Prevent white spot lesions from occurring
- Buffer acids produced by bacteria and plaque
- Strengthen enamel making it more resistant to white spot lesions

After your bands are removed, MI Paste will:

- Remineralize white spots
- Optimize the tooth enamel's appearance
- Increase the reflectivity of the enamel surface

Available in five delicious flavors, MI Paste with RECALDENT™ (CPP-ACP) can help you strengthen, protect and condition your teeth. Ask your dentist or hygienist how it can help you enjoy a smile that lasts a lifetime.

MI Paste™ and MI Paste Plus™ Helps Prevent Dry Mouth

Saliva is your body's natural oral defense system, delivering important minerals to your teeth to keep them strong and healthy, but many factors can limit or reduce your ability to produce saliva, including:

- Aging
- Reactions to medications
- Disease
- Chemotherapy
- Stress

Without saliva, you can suffer a mineral imbalance that leads to increased risk of tooth disease.

The Solution

MI Paste™ with RECALDENT™ (CPP-ACP):

- Delivers calcium and phosphate when and where they are needed most
- Binds minerals to tooth surfaces, plaque and soft tissue
- Corrects the mineral balance
- Improves saliva flow and fluoride uptake
- Relieves dry mouth

Available in five delicious flavors, MI Paste with RECALDENT™ (CPP-ACP) can help you strengthen, protect and condition your teeth. Ask your dentist or hygienist how it can help you enjoy a smile that lasts a lifetime.

MI Paste™ and MI Paste Plus™ Helps Soothe Bleaching and Whitening Tooth Sensitivity

It is wonderful to flash a bright, white smile, but tooth-whitening procedures can lead to sensitivity.

The Solution

MI Paste™ with RECALDENT™ (CPP-ACP) reduces sensitivity in just minutes by:

- Delivering calcium and phosphate to provide a protective covering for dental nerve endings
- Helping remineralize your teeth and restore a healthy oral mineral balance
- Buffering plaque acid as it reduces sensitivity
- Restores oral balance
- Helps to prevent shade loss

Available in five delicious flavors, MI Paste with RECALDENT™ (CPP-ACP) can help you strengthen, protect and condition your teeth. Ask your dentist or hygienist how it can help you enjoy a smile that lasts a lifetime.

MI Paste and MI Paste Plus Helps

Pregnancy, especially if you're nauseated, can produce high oral acid levels that can lead to tooth enamel erosion.

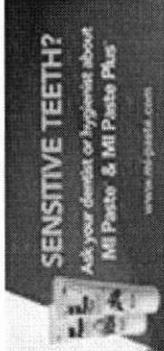
Contraindications

- Casein phosphopeptides are derived from milk. DO NOT use on patients with a proven or suspected milk protein allergy and/or with a sensitivity to benzoate preservatives.
- RECALDENT (CPP-ACP) is a milk derived with lactose content less than 0.01%.
- Due to the fluoride, MI Paste Plus is not recommended on patients under the age of six (6). MI Paste would be recommended.



ask dr. chiann

Let Mrs. USA help improve your smile



Watch Amy Nieves RDH, GC America MI Specialist interview at recent dental hygiene show!



Contact Us

As Seen on TV

GC America - Professional Dental Site | View the NEW MI Paste Commercial | Corporate Profile | Privacy Statement | As seen in the NY Daily News



Key Engineering Materials Vols. 284-286 (2005) pp. 35-38
online at <http://www.scientific.net>
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The Effect of Hydroxyapatite on the Remineralization of Dental Fissure Sealant

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Keywords: Bonding Strength, Dental Fissure Sealant, Hydroxyapatite, Remineralization

Abstract. The purpose of this study is to investigate the remineralization of enamel in the human tooth by fissure sealant containing various amount of hydroxyapatite. Prior to remineralization experiments, the necessary requirements of the dental fissure sealant, the curing depth and the curing time, were measured with the content of the hydroxyapatite according to the standard of ISO 6874. Various amount of hydroxyapatite was mixed uniformly using sonicator up to 20 wt% to the fissure sealant. In spite both the curing time and the curing depth were decreased with increasing the content of hydroxyapatite, all samples were satisfied the ISO requirements. Remineralization experimental samples were produced by bonding fissure sealant containing various amount of hydroxyapatite to human tooth enamel using manufacturer's information. After exposure to the simulated body fluid at 36.5°C for 4 weeks, the bonding strength and the surface morphology were examined using Instron and scanning electronic microscope, respectively. The bonding strength between the fissure sealant and the human teeth was drastically enhanced with the amount of hydroxyapatite. The remineralization zone could be observed along with the boundary of hydroxyapatite and fissure sealant using a scanning electronic microscope.

Introduction

The main component of fissure sealant is Bis-GMA resin. Fissure sealant, a dental esthetic material, is used for caries prevention. However, in many cases, fissure sealant is fallen out because of the microleakage between the fissure sealant and tooth. Bacterial invasion is produced through the microleakage and then the secondary dental caries is produced. Many clinicians try to minimize the microleakage in dental esthetic restoration in order to protect the dental caries.

Hydroxyapatite(HA) is known to remineralize the tooth when applied to the enamel surface. On the basis of this, HA was added to the fissure sealant to induce the remineralization effect between the enamel interface, thereby eliminating the microleakage and enhancing the bonding strength. [1]

To provide an environment similar to intraoral, test specimens were maintained at 36.5°C similar to body temperature in simulated body fluid(SBF) which has a composition as saliva. The Ca ions and the P ions in the saliva have a great solubility and therefore mineralization and remineralization take place easily. [2, 3] The previous studies implicated that the action of Ca or P ions in the saliva, assist the HA particles to undergo remineralization and become one body with the surrounding enamel. For this study, the remineralization effect can be expected to improve the adhesion between dental material and human tooth. The purpose of this study is to investigate the remineralization of enamel in the human tooth by the fissure sealant mixed with various amount of hydroxyapatite.

Materials and Methods

Commercially available dental fissure sealant and HA were purchased to prepare the composite of fissure sealant and HA. Concise™ (3M/ESPE, USA) was selected in this study with a light curing source (XL 3000, 3M/ESPE, USA). Various amount of HA (Sigma-Aldrich Inc., USA) was mixed uniformly using sonicator up to 20 wt% to the fissure sealant. For equal distribution of the mixed hydroxyapatite, Sonicator (SH-2100) was used for sonication. Air bubble was completely removed in a vacuum oven below 50°C. The pure Concise™ was used as the control.

The curing depth and the curing time were determined as a necessary requirement of the dental fissure sealant in accordance with ISO 6874. Total 80 specimens were prepared for the measurement of the bonding strength between fissure sealant and the human teeth. Experimental specimens were produced by bonding fissure sealant containing various amount of hydroxyapatite to human tooth enamel using manufacturer's information. The polyethylene tube (diameter - 5mm) was used to bond the fissure sealant to the enamel. All specimens were immersed into the simulated body fluid at 36.5°C for 4 weeks. The bonding strength was determined using universal testing machine (Instron, UK). The statistical significant differences were analyzed by Mann-Whitney U test. The surface and cross-section of the specimens were observed using SEM (S 2000, Hitachi, Japan).

Result

The curing time of the fissure sealant was decreased with increasing HA content (Fig. 1). More than 10% of HA showed significant difference ($P < 0.05$). The curing depth of the fissure sealant was decreased slightly with increasing HA content; however, there was no significant difference ($P > 0.05$) (Fig. 2). All the samples containing any amount of HA were satisfied the requirement of ISO either curing time or curing depth. The bonding strength was drastically increased with increasing HA content (Fig. 3). More than 5% of HA showed significant difference ($P < 0.05$). The maximum strength was reached 126 MPa when 20% of HA, which is 17% higher than without HA.

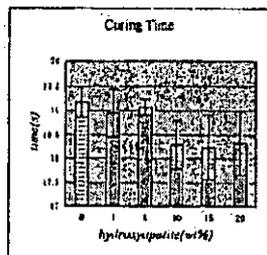


Fig. 1. Curing time.

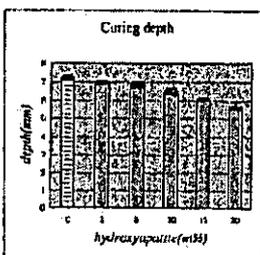


Fig. 2. Curing depth.

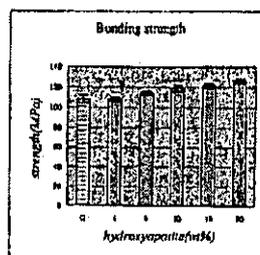
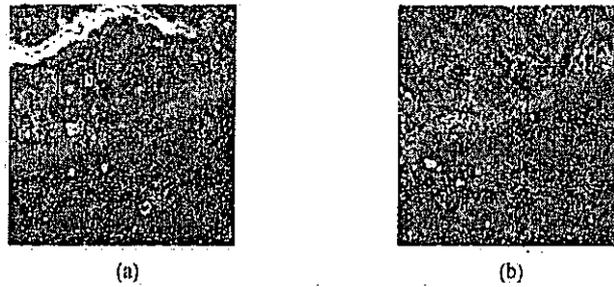
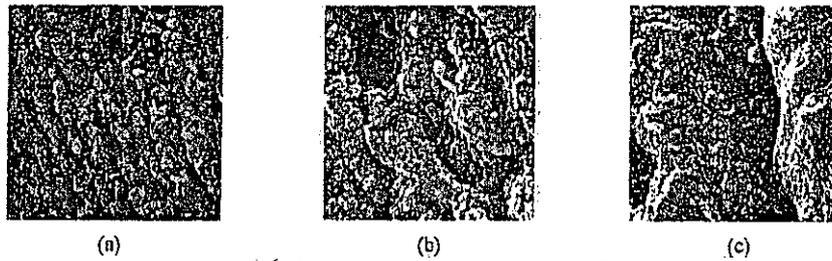


Fig. 3. Bonding strength.

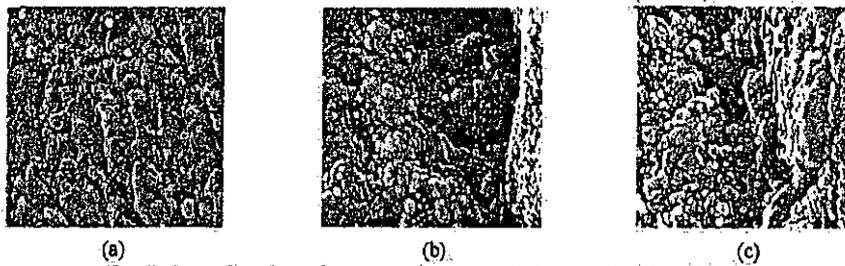
According to the observation by SEM, the remineralized zone could be observed along with the interface between HA and fissure sealant, while there was no sign of remineralization without HA (Fig. 5). This remineralized zone could be seen more clearly as the amount of HA increased. The remineralized zone is neither enamel nor sealant as a result of the elementary analysis. Under SEM, an amorphous white zone was seen in the interface between the tooth and the sealant. This interface was not distinct but it seemed to be the remineralization zone. Under SEM, it seemed to be recrystallization of hydroxyapatite in enamel surface of experimental group compared with that of without HA.



(a) (b)
Fig. 5. Interface between the tooth and the sealant. by SEM ($\times 1000$)
(a) experimental group – hydroxyapatite 20 wt% (b) control group



(a) (b) (c)
Fig. 6. Enamel surface of control group by SEM:
(a) ($\times 2000$) (b) ($\times 10000$) (c) ($\times 20000$)



(a) (b) (c)
Fig. 7. Enamel surface of experimental group – hydroxyapatite 20 wt% by SEM
(a) ($\times 2000$) (b) ($\times 10000$) (c) ($\times 20000$)

Discussion & conclusion

An ideal dental esthetic material requires adequate physicochemical characteristic, biocompatibility, sustainability and anticariogenic effect to restore esthetic and masticatory function. In this study, HA was added to a commercial fissure sealant Concise™ up to 20 wt%. To find out the physical

characteristics of this newly made sealant, the curing time, curing depth and the bonding strength was compared with the control. And the remineralization effect of hydroxyapatite on the enamel surface was observed under SEM.[3,4,5]

According to the result, we can predict the adhesion between the fissure sealant and tooth was enhanced. The new composite sealant has a remineralization effect against microleakage and bacterial invasion. The new composite sealant can challenge the concept of dental caries prevention by enhancing the adhesion of sealant and tooth.

In conclusion:

1. The curing time and the depth were in the range of ISO standard which did not affect the physical characteristics.
2. As the content of HA increases the bonding strength between the sealant and the tooth surface tend to show an increase.
3. Under SBF, HA in the sealant showed a remineralization effect in the interface with the enamel forming a hybrid layer.

If the new hydroxyapatite composite sealant was treated in adequate time, that of the longevity and caries prevention would be improved. In addition to the bonding strength of the sealant containing the hydroxyapatite, long term observation and an assessment of the microleakage with a dye would support this study.

References

- [1] P. Andersona : Archives of Oral Biology (2004) 49, 199 - 207
- [2] Rui Vitorino: Biochemical and Biophysical Research Communications 320 (2004), p.342-346
- [3] C. Santos: Biomaterials Volume 23, Issue 8 (2002), p.1897-1904
- [4] Sabine H. Dickens: Dental Materials Volume 19 (2003), p.558-566
- [5] C. Domingo: Journal of Biomedical Materials Research Volume 56 (2001), p. 297 - 305



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Mr. M. Th. Plaumann
Managing Board
VOCO GMBH
Anton-Flettner-Strasse 1-3
Cuxhaven Germany D-27472

OCT 21 2010

Re: K101104
Trade/Device Name: VOCO Paste
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: September 27, 2010
Received: September 29, 2010

Dear Mr. Plaumann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2- Mr. Plaumann

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 101104

Device Name: VOCO Paste

OCT 21 2010

Indications for Use:

VOCO Paste is intended to be used after professional tooth whitening, professional tooth cleaning and for prevention and control of hypersensitivities.

Prescription Use

OR

Over-The-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101104



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 08, 2010

VOCO GMBH
ANTON-FLETTNER-STRASSE 1-3
CUXHAVEN
GERMANY D-27472
ATTN: M. TH PLAUMANN

510k Number: K101104

Product: REMIN PRO

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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records processed under FOIA Request # 2014-5495; Released by CDRH on 06-29-2016
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 20, 2010

VOCO GMBH
ANTON-FLETTNER-STRASSE 1-3
CUXHAVEN
GERMANY D-27472
ATTN: M. TH PLAUMANN

510k Number: K101104
Received: 4/20/2010
Product: REMIN PRO

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

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

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K101104

VOCO GmbH • Postfach 767 • 27457 Cuxhaven • Germany

FDA CDRH DMC

VOCO

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue.

APR 20 2010

Received

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Fax: +49 (0)4721-719-109

info@voco.de
www.voco.de

Silver Spring, MD 20993-0002
U. S. A.

K-62

Dr. TG/KFr

16/04/2010

Re.: Traditional 510 (k) submission for the preparation Remin Pro

Dear Madams/Sirs,

We hereby like to apply for the listing of a dental medical device with the FDA.

Please find enclosed the traditional 510(k) submission for the preparation **Remin Pro** for your kind consideration.

In case of any questions or if you need additional documents, please feel free to contact the undersigning person by mail (t.gerkensmeier@voco.de) phone (+49-4721-719-200 or fax (+49-4721-719-219) for more information..

Many thanks for your help and cooperation,

with best regards
VOCO GmbH


Dr. Thorsten Gerkensmeier
(Regulatory Affairs)

Enclosures

DS
X

132

Traditional 510(k) submission for the preparation

Remin Pro



Research & Development

VOCO GmbH

Anton-Flettner-Str. 1-3, D-27472 Cuxhaven (Germany)

Tel.: +49-4721/719-0 FAX: +49-4721/719-109 e-mail: info@voco.de

Section 1

Medical Device User Fee Cover Sheet (Form FDA 3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) VOCO GMBH Anton-Flettner-Str. 1-3 Cuxhaven Lower Saxony 27472 DE 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Manfred Thomas Plaumann 2.1 E-MAIL ADDRESS mth.plaumann@voco.de 2.2 TELEPHONE NUMBER (include Area code) 49-4721-719-0 2.3 FACSIMILE (FAX) NUMBER (Include Area code) +49-4721-719-219
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)	
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)	

02-Feb-2010

Records processed under FOIA Request # 2014-5495; Released by CDRH on 06-29-2016

Records processed under FOIA Request # 2014-5495; Released by CDRH on 06-29-2016

Section 2

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
--	---

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name VOCO GmbH	Establishment Registration Number (if known) 8010908		
Division Name (if applicable)	Phone Number (including area code) (+49) (0)4721-719-0		
Street Address Anton-Flettner-Str. 1-3	FAX Number (including area code) (+49) (0)4721-719-219		
City Cuxhaven	State / Province	ZIP/Postal Code 27472	Country Germany
Contact Name M. Th. Plaumann			
Contact Title Managing Board		Contact E-mail Address mth.plaumann@voco.de	

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

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

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Other Reason (specify):				

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

SECTION E ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input type="checkbox"/> 510 (k) summary attached <input checked="" type="checkbox"/> 510 (k) statement
1 EJR	2	3	4	
5	6	7	8	

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K070854	GC MI Paste Plus	GC America, Inc.
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device	Model Number
1	Remin Pro	1
2		2
3		3
4		4
5		5

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

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

Data included in Submission Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code EJR	C.F.R. Section (if applicable) 8726030	Device Class <input checked="" type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Dental		

Indications (from labeling)

Indications:

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

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

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name VOCO GmbH			Establishment Registration Number 8010908		
Division Name (if applicable)			Phone Number (including area code) (+49) (0)4721-719-0		
Street Address Anton-Flettner-Str. 1-3			FAX Number (including area code) (+49) (0)4721-719-219		
City Cuxhaven		State / Province	ZIP/Postal Code 27472	Country Germany	
Contact Name M. Th. Plaumann		Contact Title Managing Board		Contact E-mail Address mth.plaumann@voco.de	

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

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

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SECTION I UTILIZATION OF STANDARDS

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

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

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

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

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

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

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Premarket Notification [510 (k)] Cover Letter

(April 14, 2010)

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

Subject: Traditional Premarket Notification Submission for the preparation
"Remin Pro"

Submission according to "Guidance for Industry and FDA Staff"

Dear Sir:

This is to submit a traditional premarket notification submission pursuant to notifying the Food and Drug Administration that VOCO GmbH intends to introduce **Remin Pro**, a paste for advanced re-mineralization of oral hard tissue surfaces into U.S. interstate commerce for commercial distribution.

Confidentiality Statement

VOCO GmbH requests that the FDA disclose no specific product information, nor any administrative information regarding the progress of this marketing application, to anyone other than authorized FDA officers and employees, officers employed by VOCO GmbH, or the U.S. Designated Agent. Specific product information, such as its chemical composition, performance data or product performance data, is proprietary and not to be disclosed publicly without a written statement of approval by an officer of VOCO GmbH.

Establishment Registration Number

8010908

Device Trade Name

Remin Pro

Device Classification

Agent, Polishing, Abrasive, Oral Cavity

Device CFR Section

21 CFR 872.6030

FDA Device Class

Class II (Special Controls)

FDA Product Code

EJR

Classification Panel

76 Dental

Device to which Grandioso is claimed Substantially Equivalent

GC MI Paste Plus, K070854, GC America

Device Indications

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

Contact Information

If there are any questions you may contact Manfred Thomas Plaumann, Managing Board for VOCO GmbH by telephone at + 49 (4721) 719-200 or e-mail at mth.plaumann@voco.de

Indications for Use Statement

510(k) Number: _____

Device Name: Remin Pro

Indications for Use:

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

Prescription Use X

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5

510(k) Summary or 510(k) Statement

**PREMARKET NOTIFICATION
510(k) STATEMENT
(As Required By 21 CFR 807.93)**

I certify that, in my capacity as Managing Director of VOCO GmbH, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



(Signature of Certifier)

Mr. Manfred Thomas Plaumann

(Typed Name)

April 14, 2010

(Date)

(Premarket Notification [510(k)] Number)

Section 6

Truthful and Accurate Statement

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required By 21 CFR 807.87(k)]**

I certify that, in my capacity as the Managing Director of VOCO GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Manfred Thomas Plaumann (Managing Board)

(Typed Name)

April 14, 2010

(Date)

Premarket Notification [510(k)] Number

Section 7

Summary Report

Remin Pro will be offered in the following presentations:

- 40g tube available as mint, melon and strawberry

Remin Pro is intended for use as:

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

Remin Pro is claimed to be substantially equivalent to **GC MI Paste Plus** (K070854, GC America)

For details of product performance data please see section 9 (substantial equivalence comparison).

Subject device: **Remin Pro**

Predicate devices: **GC MI Paste Plus (K070854, GC America)**

Basis for claiming substantial equivalence:

Remin Pro is substantially equivalent to **GC MI Paste Plus** with respect to:

- intended use
- composition
- product performance

Similarity of intended use:

Indications for use	
Remin Pro (subject device)	GC MI Paste Plus (predicate device)
<ul style="list-style-type: none"> - following in-office bleaching procedures - after ultrasonic, hand scaling or root planing - following professional tooth cleaning - hypersensitivity prevention and control - as an alternative means of applying fluoride topically in children aged 6 and above - during orthodontic treatment - for high risk caries patients - to provide a topical for patients suffering from erosion, xerostomie or Sjögrens syndrome - for special needs adult patients 	<ul style="list-style-type: none"> - for patients who suffer from aggressive caries and loss of tooth structure, from dental erosion and accelerated tooth wear following head and neck radiotherapy - for pregnant women - during and/or after orthodontics - for patients with an acidic oral environment and gastric reflux - for patients with poor plaque control and high caries risk

Compositional similarity of Remin Pro and the predicate device GC MI Paste Plus

Both preparations serve the same purpose, thus, the components are functionally equivalent. The ingredients are chemically comparable as well featuring similar properties.

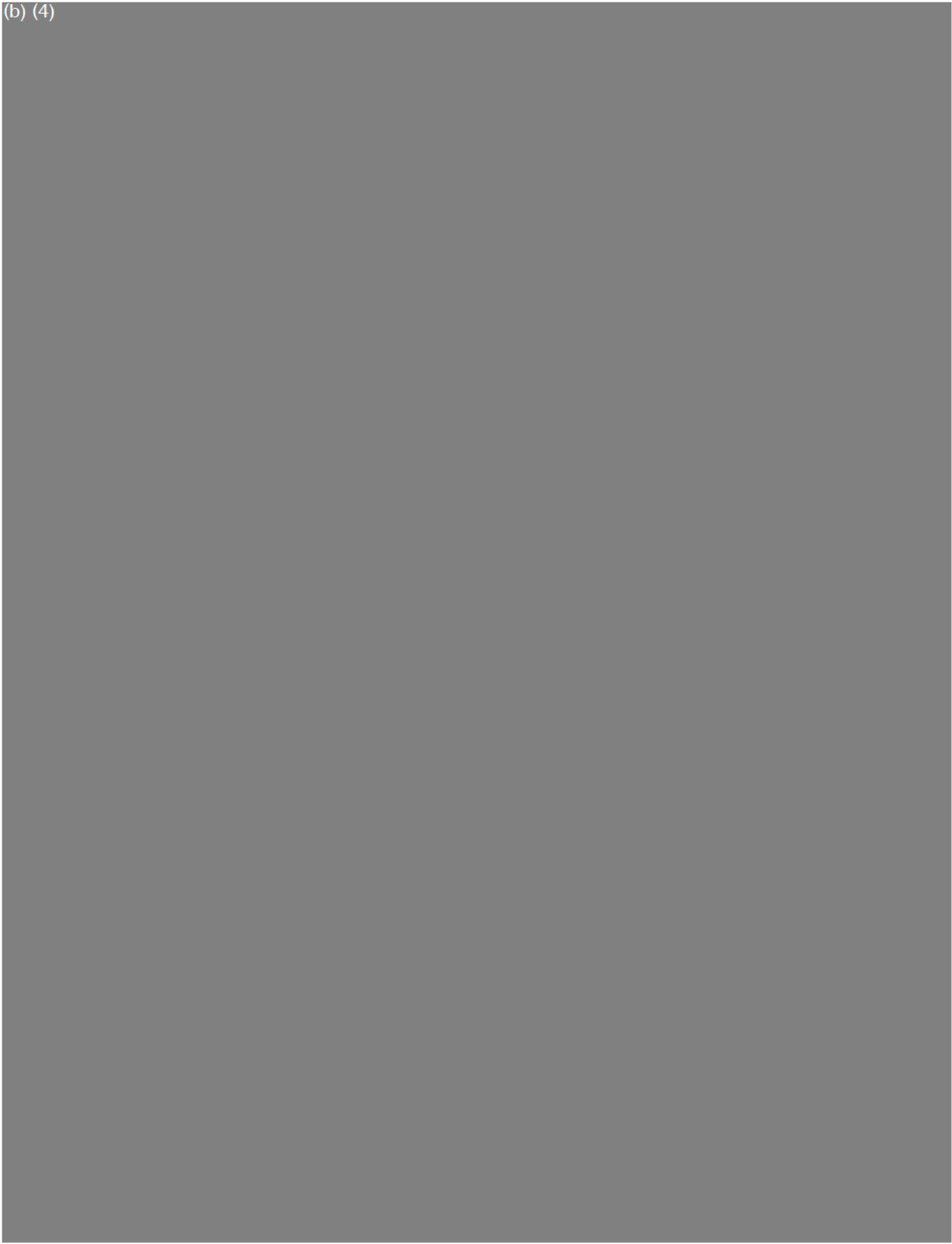
Function	Ingredient	Remin Pro	GC MI Paste Plus
Inert Filler	Pigments	(b) (4)	
Stabilizer	Parabene		
Matrix	Glycerine		
	Water		
	Propyleneglycol		
Thickener	Carboxymethylcellulose		
	Silica		
Remineralization Support	Phosphoric acid		
	CPP-ACP		
	Hydroxylapatite		
	Sodium Fluoride		
Additives	Sweetener		
	Flavors		

Remin Pro and the predicate device feature components which are intended to support the remineralization of human enamel and dentin.

The prior use of all of the components of **Remin Pro** in legally marketed devices support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

**Product performance data for Remin Pro and the predicate device
GC MI Paste Plus:**

(b) (4)

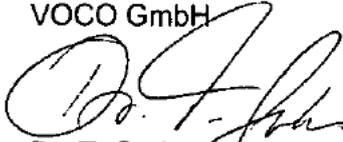


(b) (4)



Cuxhaven, dated April 14, 2010

VOCO GmbH



Dr. T. Gerkersmeier
Scientific Dept.

VOCO GmbH
Anton-Flettner-Str. 1-3
27472 Cuxhaven
Germany



(b) (4)



Records processed under FOIA Request # 2014-5495; Released by CDRH on 06-29-2016

Records processed under FOIA Request # 2014-5495; Released by CDRH on 06-29-2016

Records processed under FOIA Request # 2014-5495; Released by CDRH on 06-29-2016

Section 10

Proposed Labeling

DEVICE LABELING PRESCRIPTION DEVICE CAUTION STATEMENT

In accordance with Title 21 Code of Federal Regulations (CFR) Part 801.109(b)(1), the label information for this device will clearly bear a Prescription Device Caution Statement, as follows:

"Caution: Federal laws restrict this device to sale by or on the order of a dentist."

Remin Pro
Protective dental care
with fluoride and hydroxy apatite
Schützende Zahnpflege
mit Fluorid und Hydroxylapatit

Remin Pro
Protective dental care
with fluoride and hydroxy apatite
Schützende Zahnpflege
mit Fluorid und Hydroxylapatit

FR: soin des dents avec effet protecteur aux fluorures et à l'hydroxyapatite ES: cuidado dental protector con fluoruro e hidroxapatita PT: cuidado e proteção das dentes com fluor e hidroxapatita IT: Protezione dentale con fluoro e idrossapatite NL: Beschermende tandzorg met fluoride en hydroxyapatiet DE: Zahngesundheit mit Fluorid und Hydroxylapatit GB: Zahngesundheit mit Fluorid und Hydroxylapatit RO: Îngrijirea dentară cu fluorură și hidroxiapatit GR: Προστατευτική οδοντοπροστασία με φθορίδιο και υδροξυαπατίτη UA: Догляд за зубами з використанням фтору та апаїту та гідроксиду апатиту PL: Lecznicza pielęgnacja zębów z fluorami i hydroksyapatytem CZ: ochrana péči o chrupu s fluoridem a hydroxylapatitem HU: Fluorid és hidroxiapatit tartalmú védőszappan DK: Sættelsesmiddel med stannol og fluorid og hydroxylapatit LI: Präfektive dentale staunges pflegemittel mit fluoreid und hydroxylapatit zoba koptarrea fitzabak ar fluorida un hidroksilapatita

Made in Germany
NET WT. 3 x 40 g



VOCO GmbH, P.O. Box 757, D-457 32 Heessen, Germany

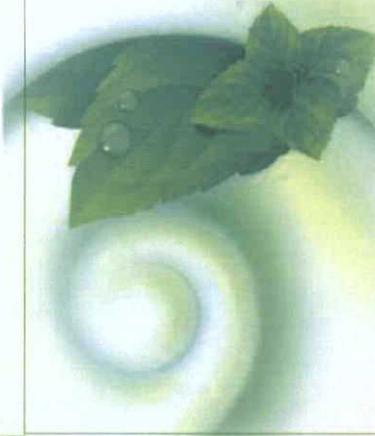
W 70 000007 51 0010 4

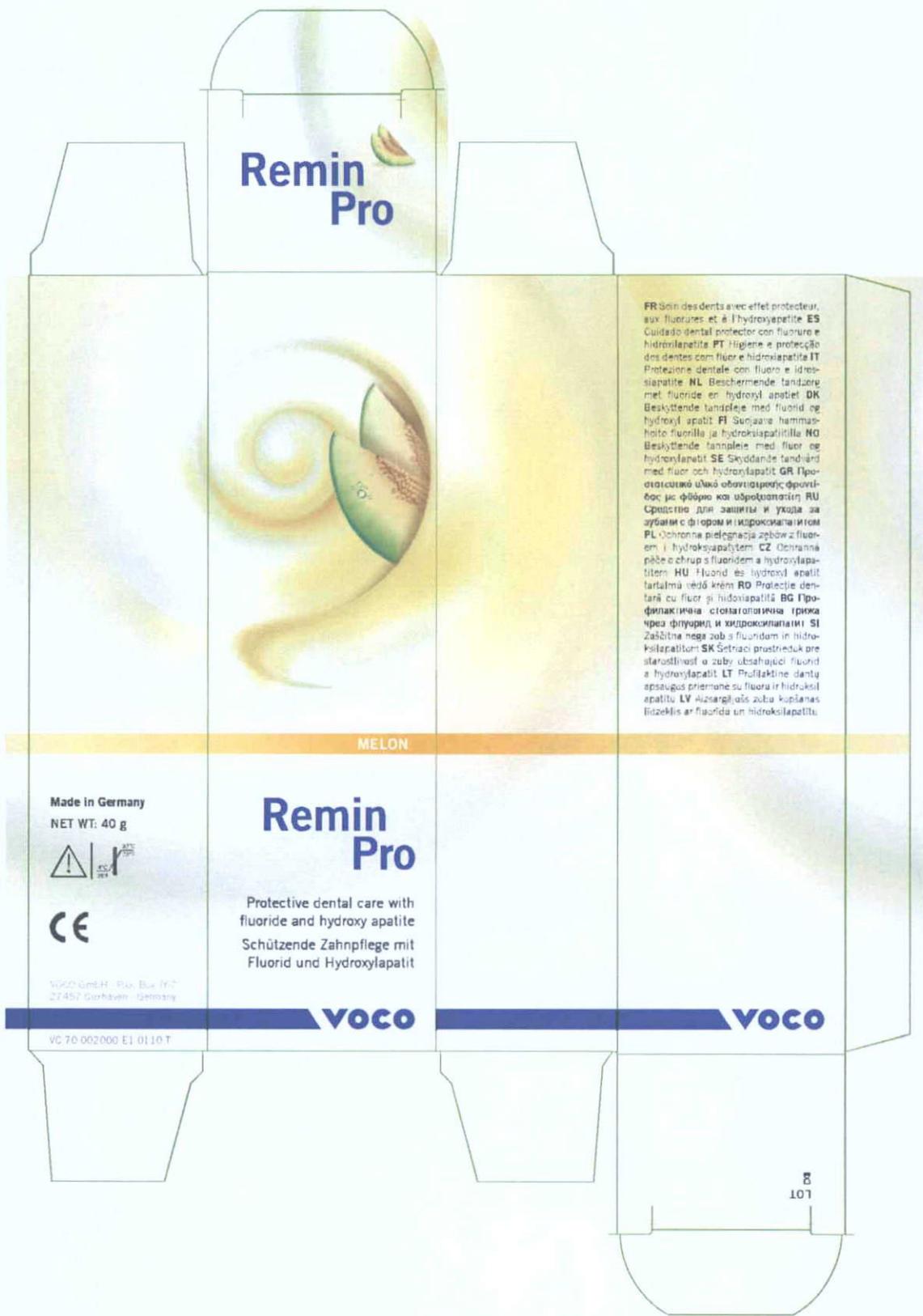
VOCO

VOCO

Remin Pro

Protective dental care with fluoride and hydroxy apatite
Schützende Zahnpflege mit Fluorid und Hydroxylapatit





FR Soins des dents avec effet protecteur, aux fluorures et à l'hydroxyapatite ES Cuidado dental protector con fluoruro e hidroxiapatita PT Higiene e protecção dos dentes com flúor e hidroxiapatita IT Protezione dentale con fluoro e idrossiapatite NL Beschermende tandzorg met fluoride en hydroxyl apatiet DK Beskyttende tandpleje med fluorid og hydroxyl apatit FI Suojaine hammashoito fluorilla ja hydroksiapatitilla NO Beskyttende tannpleie med fluor og hydroxylapatit SE Skyddande tandvård med fluor och hydroxylapatit GR Προσταστική ύλεα οδοντολογικής φρονιδας με φθοριο και υδροξυαπατιτη RU Средство для защиты и ухода за зубами с фтором и гидроксиапатитом PL Ochronna pielęgnacja zębów z fluorem i hydroksiapatytem CZ Ochrana pébe o chrup s fluoridem a hydroxylapatitem HU Fluorid és hydroxyl apatit tartalmú védő krém RO Protecție dentară cu fluor și hidroxiapatită BG Профилактична стоматологична грижа чрез флуорид и хидроксиапатит SI Zaščitna nega zob s fluoridom in hidroksiapatitom SK Šetrná prostriedok pre starostlivosť o zuby obsahujúci fluorid a hydroxylapatit LT Profilaktinė dantų apsaugos priemonė su fluoru ir hidroksil apatitu LV Aizsargi zobu ar fluorīdu un hidroksiapatīti. Biželis ar fluorīdu un hidroksiapatīti.

Made in Germany
NET WT: 40 g
Warning symbol
CE
VOCO GmbH · Post-Büx 107
27457 Gehrden · Germany
VC 70.002000 E1 0110 T

Remin Pro

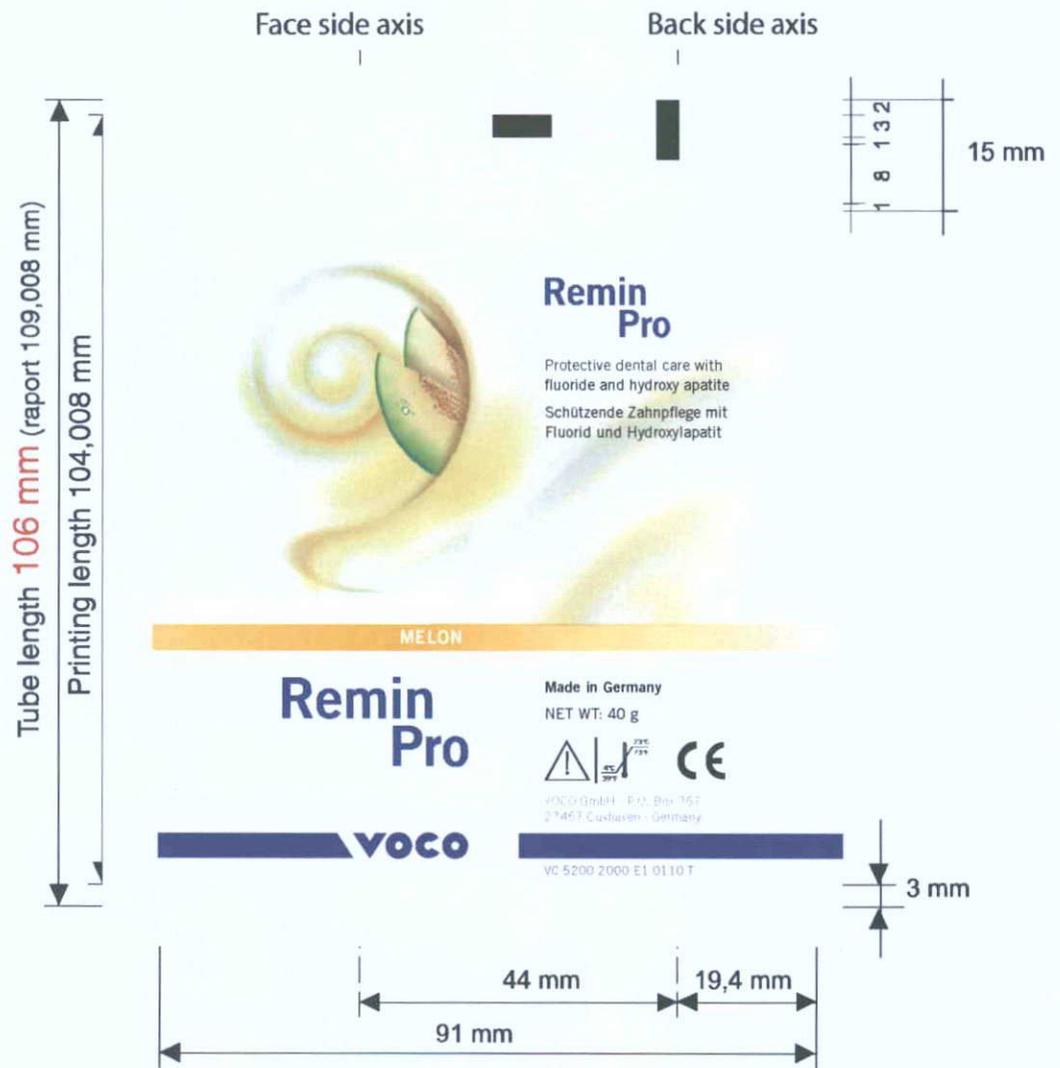
Protective dental care with fluoride and hydroxy apatite
Schützende Zahnpflege mit Fluorid und Hydroxylapatit

VOCO

VOCO

8
107

174



Laminate format \varnothing 28 mm (91 x 109,008 mm)

Printing format (80 x 104,008mm)

Colours:

„Melon Yellow“

Cyan: 0%
Magenta: 30%
Yellow: 100%
Black: 0%

„VOCO Blue“

Cyan: 100%
Magenta: 80%
Yellow: 0%
Black: 20%



Remin
Pro

FR Soins des dents avec effet protecteur aux fluorures et à l'hydroxyapatite ES Cuidado dental protector con fluoruro e hidroxapatita PT Higiene e protecção dos dentes com fluor e hidroxapatita IT Protezione dentale con fluoro e idrossiapatite NL Beschermende tandzorg met fluoride en hydroxyl apatiet DK Beskyttende tandpleje med fluorid og hydroxyl apatit FI Suojaa hammasholto fluorilla ja hydroksiapatitilla NO Beskyttende tannpleie med fluor og hydroxyapatit SE Skyddande tandvård med fluor och hydroxylapatit GR Προστατευτικό υλικό οδοντομετρικής φροντίδας με φθορίο και υδροξυapatίτη RU Средство для защиты и ухода за зубами с фтором и гидроксиапатитом PL Ochronna pielęgnacja zębów z fluorem i hydroksiapatytem CZ Ochranná péče o chrup s fluoridem a hydroxylapatitem HU Fluorid és hydroxyl apatit tartalmú védő krém RO Protecție dentară cu fluor și hidroxapatită BG Профилактична стоматологична грижа чрез флуорид и хидроксиапатит SI Zaščitna nega zob s fluoridom in hidroksiapatitom SK Sebnaci prášok na ochranu zubov s fluoridom a hydroxylapatitom LT Profilaktinė dantų apsaugos priemonė su fluoru ir hidrokali apatitu LV Aizsarglīdzis zobu kopšanai līdzējis ar fluorīdu un hidroksiapatīti

MINT

Made in Germany
NET WT. 40 g



CE

VOCO GmbH - P.O. Box 767
27457 Guxhagen - Germany

Remin
Pro

Protective dental care with
fluoride and hydroxy apatite
Schützende Zahnpflege mit
Fluorid und Hydroxylapatit

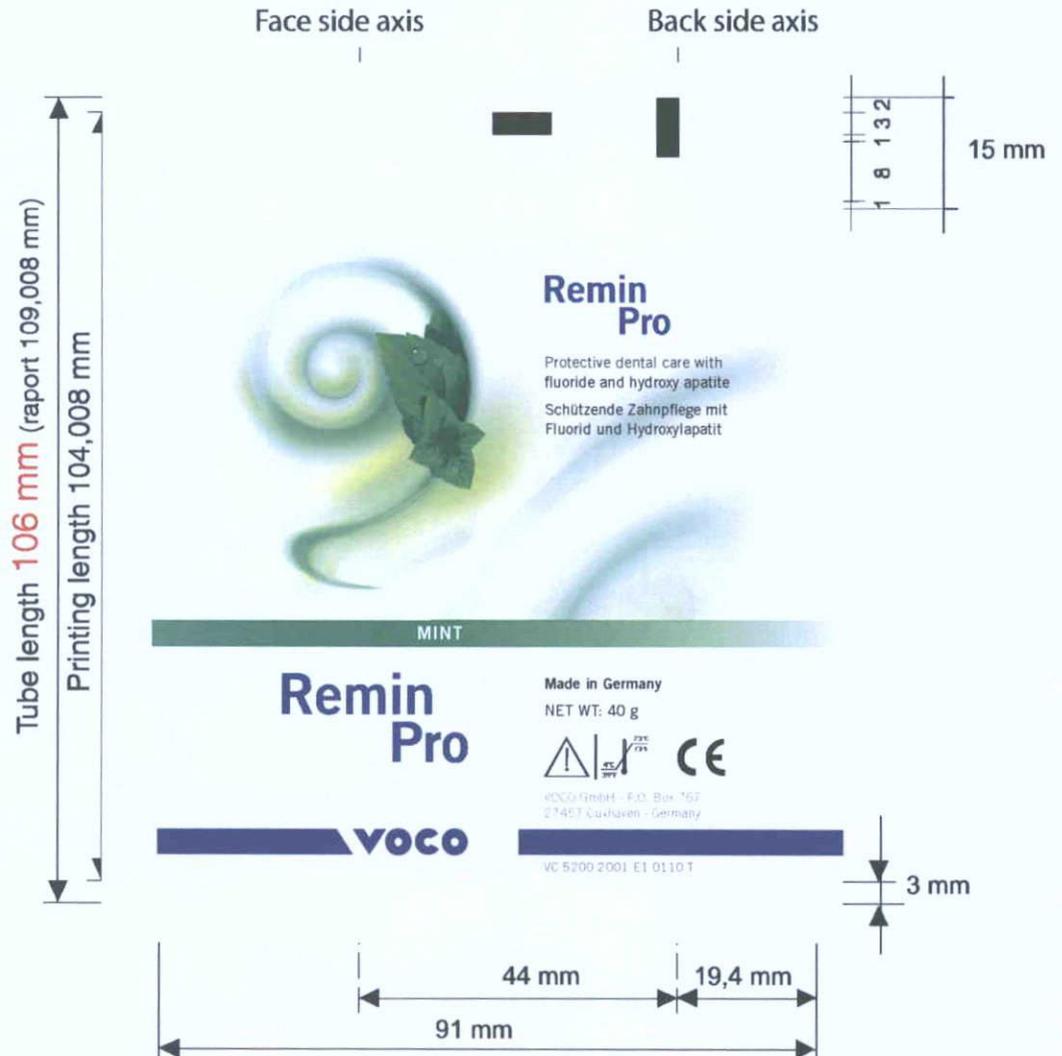
VOCO

VOCO

VC 70 002001 E1 0110 T

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176



Laminate format \varnothing 28 mm (91 x 109,008 mm)

Printing format (80 x 104,008mm)

Colours:

„Mint Green“	„VOCO Blue“
Cyan: 75%	Cyan: 100%
Magenta: 0%	Magenta: 80%
Yellow: 100%	Yellow: 0%
Black: 0%	Black: 20%



Remin Pro

FR Soins des dents avec effet protecteur, aux fluorures et à l'hydroxyapatite. ES Cuidado dental protector con fluoruro e hidroxilapatita. PT Higiene e protecção dos dentes com flúor e hidroxiapatite. IT Protezione dentale con fluoro e idrossiapatite. NL Beschermende tandzorg met fluoride en hydroxyl apatiet. DK Beskyttende tandspleje med fluorid og hydroxyl apatit. FI Suojaa hammushoito fluorilla ja hydroksiapatitilla. NO Beskyttende tannpleie med fluor og hydroxylapatit. SE Skyddande tandvård med fluor och hydroxylapatit. GR Προστατευτικό υλικό οδοντιατρικής φροντίδας με φθορίο και υδροξυapatίνη. RU Средство для защиты и ухода за зубами с фтором и гидроксиапатитом. PL Ochronna pielęgnacja zębów z fluorem i hydroksiapatytem. CZ Ochrana péče o chrup s fluoridom a hydroxylapatitem. HU Fluorid és hydroxyl apatit tartalmú széd krém. RO Protecție dentară cu fluor și hidroxiapatită. BG Профилактична стоматологична грижа чрез флуорид и хидроксиапатит. SI Zaščita nega zob s fluoridom in hidroksiapatitom. SK Sebnáci prostriedok pre sterilizáciu a zubu obsahujúci fluorid a hydroxylapatit. LT Profilaktinė dantų apsaugos priemonė su fluoru ir hidroksil apatitu. LV Atsargājošs zuba kopšanas līdzeklis ar fluorīdu un hidroksiapatīti.

STRAWBERRY

Made in Germany
NET WT. 40 g



CE

VOCO GmbH - P.O. Box 767
27487, Cloppenburg - Germany

Remin Pro

Protective dental care with
fluoride and hydroxy apatite
Schützende Zahnpflege mit
Fluorid und Hydroxylapatit

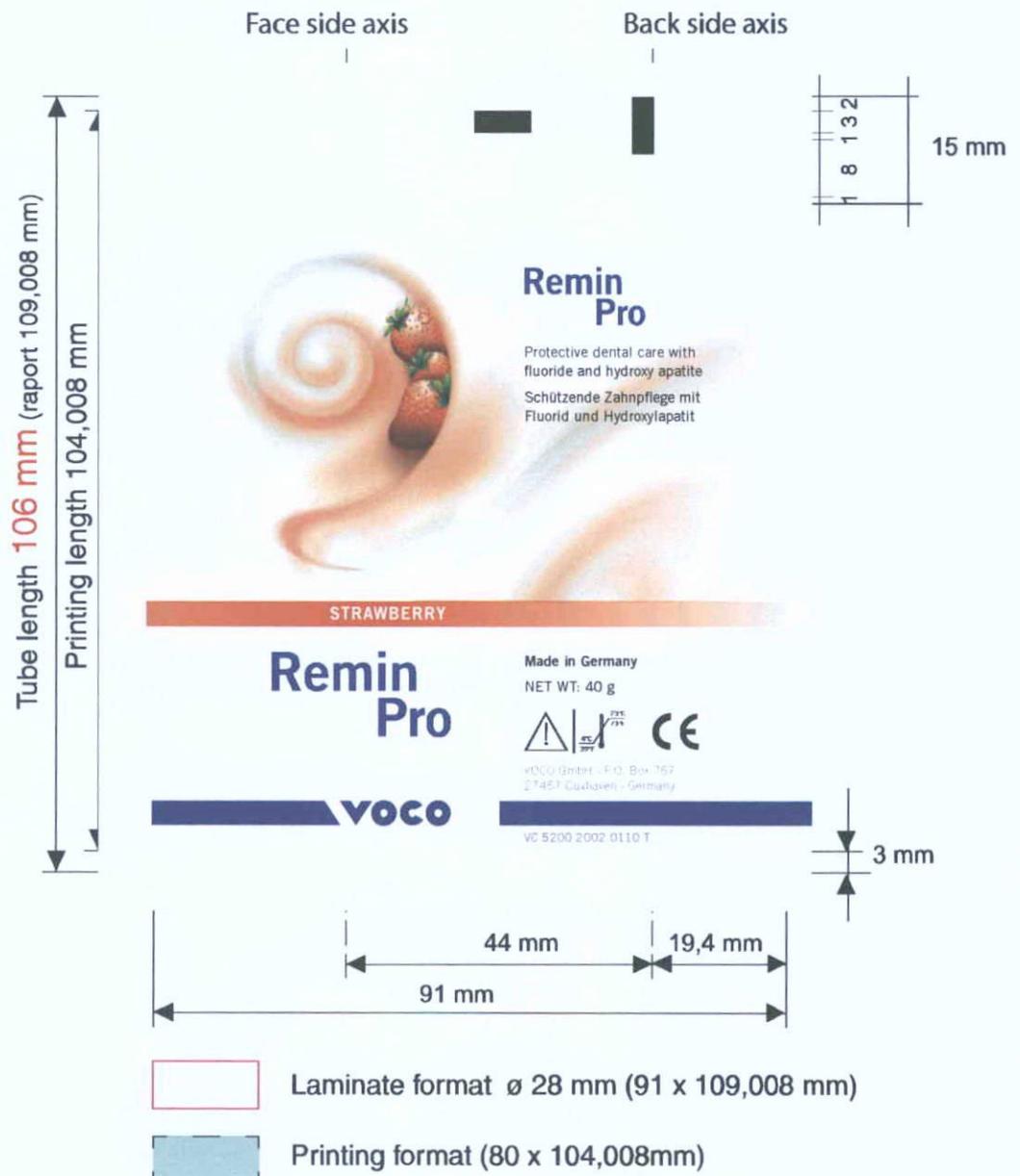
VOCO

VOCO

VC 70 002002 E1 0110 T

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107

173



Colours:

„Strawberry Red“

Cyan: 0%
 Magenta: 95%
 Yellow: 90%
 Black: 0%

„VOCO Blue“

Cyan: 100%
 Magenta: 80%
 Yellow: 0%
 Black: 20%

179

Important: Read instructions before use.
Caution: U.S. Federal Laws restrict this material to sale by or on the order of a dentist.
For dental use only.
Warning: Avoid contact with eyes and skin. If contact occurs, flush immediately with plenty of water and consult a physician.
Avoid inhalation or ingestion.
Keep out of the reach of children and do not store together with foodstuff.
Keep away from heat and ignition sources.



Manufactured by
VOCO GmbH, P.O. Box 761, 71433 Crailsheim, Germany
Tel. 01149 4727719-0, Fax 01149 4727719-140 VC 81 000001 US 104 99



Leer esmeradamente las instrucciones antes del uso

Remin Pro es una crema de base acuosa que contiene hidroxilapatita y fluor. Remin Pro está disponible en los sabores: melón, fresa y menta. Remin Pro produce una protección extra para los dientes y ayuda adicionalmente a neutralizar los ácidos de las bacterias en la placa dental. Remin Pro colabora también en la neutralización de otros ácidos en la boca.

Indicaciones:

- Después del blanqueamiento
- Después de la limpieza dental profesional
- Prevención y control de hipersensibilidades
- Durante un tratamiento ortodóncico

Aplicación:

1. Aplicar Remin Pro - en cantidad de una alubia - con el dedo o un instrumento apropiado (pápila o gotero) en los dientes deseados.
2. El Remin Pro restante debe ser distribuido bien en la boca, para un resultado óptimo debe ser aplicado por lo menos 3 minutos.
3. Salivar los restos de la crema (lo posible se debería evitar un enjuague). El paciente debería comer o beber no menos de 30 minutos después del tratamiento. También para el uso doméstico después de limpiar los dientes.

Conservación:
 Conservar en un lugar fresco y seco, protegido de la luz directa del sol (3° F - 73° F (0° - 23° C)). El material no se debe utilizar después de la fecha de caducidad.

Precauciones:

1. Cerrar el tubo inmediatamente después del uso.
2. Contiene parabenos, fluor e hidroxilapatita (calcio y fosfato). No usar en caso de alergia contra estos componentes.
3. No se recomienda el uso en pacientes menores a 6 años así como el uso doméstico en niños menores a 12 años.
4. En caso del contacto con los ojos, lavar inmediatamente con agua corriente y contactar a un médico.
5. En caso de que se presenten síntomas de un angioedema que se podría impulsar a los componentes de Remin Pro, se debería interrumpir inmediatamente el tratamiento y contactar a un médico.

Este material se desarrolló exclusivamente para el uso del odontólogo. El proceso debe ser como está indicado en la información de uso. VOCO reconoce su responsabilidad de reemplazar los productos si se muestran que están defectuosos. VOCO no acepta la responsabilidad de cualquier perjuicio o pérdida que ocasionen del uso o de la incapacidad de usar los productos. La responsabilidad de uso, es la responsabilidad del usuario de obtener el producto de acuerdo al producto para su uso intencional. El fabricante asume todo el riesgo y la responsabilidad en conexión con este. Descripciones y datos no constituyen ninguna garantía y no son obligatorias.

ATENCIÓN: La legislación americana requiere este dispositivo para venderse o al pedido del dentista.

Ninguna persona está autorizada de proveer ninguna información que desvíe de las informaciones provistas en estas instrucciones de uso.

Para preguntas o comentarios, por favor, llámen al 1-888-658-2584.

Manténgase fuera del alcance de los niños.

Sólomente para el uso odontológico.

Fabricado por:



Carefully read instructions prior to use

Remin Pro is a water-based cream that contains hydroxy apatite and fluoride. Remin Pro is available in the flavours: melon, strawberry and mint. Remin Pro provides extra protection for the teeth and additionally helps neutralise acids from bacteria in plaque. Remin Pro additionally facilitates the neutralisation of other acids in the mouth.

Indications:

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

Application:

1. Apply a pea-size amount of Remin Pro to the teeth with a finger or suitable instrument (toothbrush or swab) and distribute.
2. The patient should distribute the remaining Remin Pro in his or her mouth with the tongue. Remin Pro and the saliva should remain in the mouth for as long as possible (minimum of 3 minutes) for an optimal result.
3. The patient should spit out the remaining amount. Rinsing should be avoided if possible. The patient should wait at least 30 minutes after the treatment before eating or drinking.

Storage:
 Store Remin Pro in a cool, dry area protected from direct sunlight (35° F - 73° F (-1° C - 23° C)). Do not use the material after the expiry date.

Precautions:

1. Always close the tube immediately after use.
2. Remin Pro contains parabens, fluoride and hydroxyapatite (calcium and phosphate). Do not use in cases of known allergies to any of the ingredients.
3. The application of Remin Pro is not recommended for patients under 6 years or for home use on children under 12 years.
4. In case of contact with the eyes, flush thoroughly with plenty of water and seek medical attention.
5. Immediately discontinue treatment and seek medical attention if symptoms of angioedema occur that can be attributed to the ingredients in Remin Pro.

This material has been developed solely for use in dentistry. Processing should be done strictly according to the instructions for use. VOCO recognizes its responsibility to replace products if proven to be defective. VOCO does not accept liability for any damage or loss, directly or indirectly, stemming from the use or inability to use the products described. Before using the product, the responsibility of the user to determine the liability in connection therewith intended use. The user assumes all risk and liability in connection therewith. Descriptions and data constitute no warranty of attributes and are not binding.

CAUTION: U.S. Federal Laws restrict this device to sale by or on the order of a dentist.

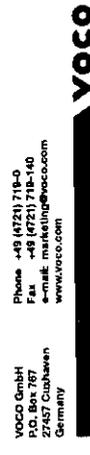
No person is authorized to provide any information which deviates from the information provided in the instructions for use.

For questions or comments, please call 1-888-658-2584.

Keep this material out of reach of children.

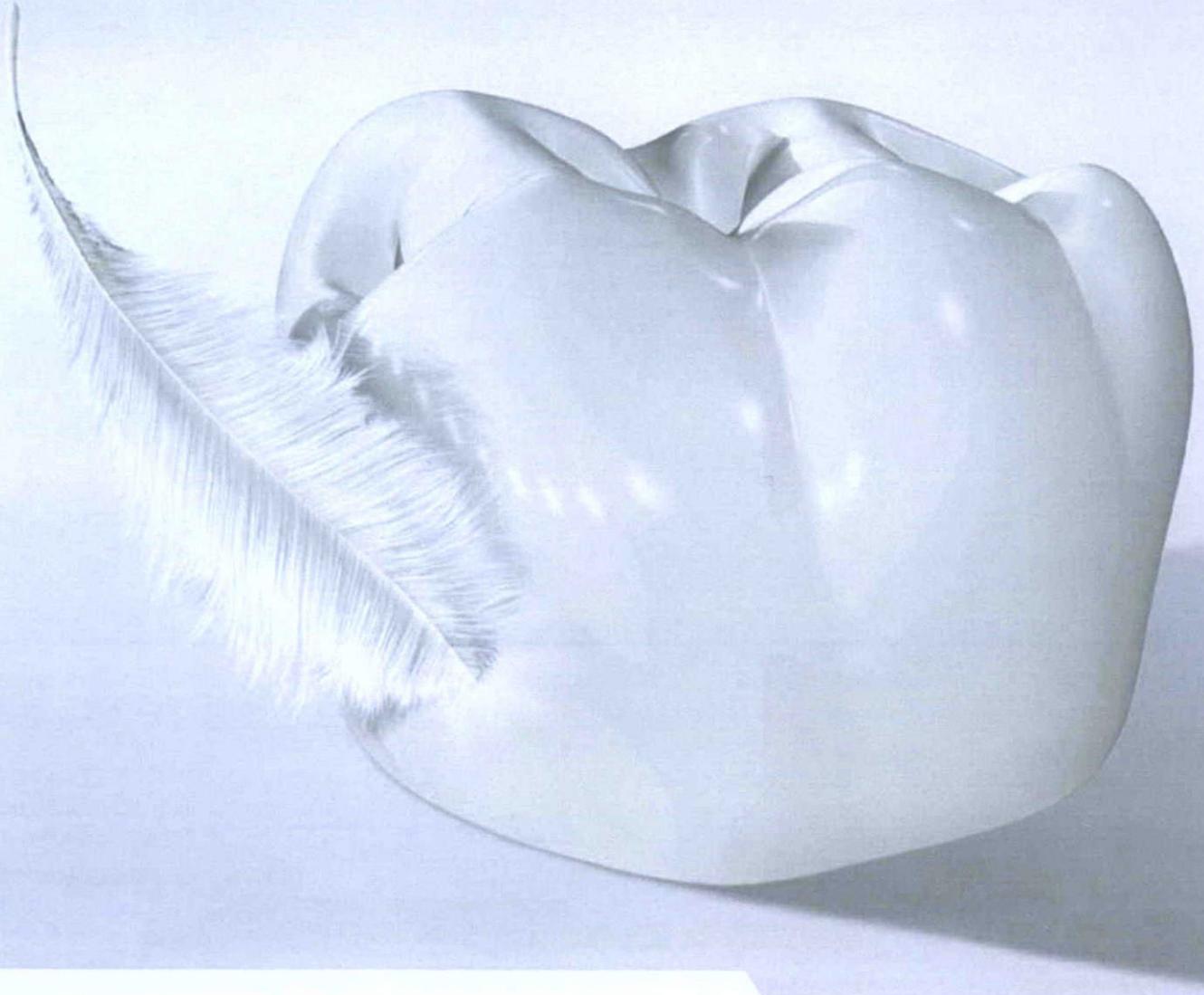
For dental use only.

manufactured by:



101

Remin Pro



Remin Pro

PROTECTIVE DENTAL CARE
WITH FLUORIDE AND HYDROXY APATITE

VOCO
THE DENTALISTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Remin Pro

RECREATION FOR THE TEETH

Remin Pro combines three equally effective components for protection against demineralisation and erosion: hydroxy apatite, fluoride and xylitol. Remin Pro represents an optimal addition to services offered by your practice!

Hydroxy apatite

Natural tooth substance consists of hydroxy apatite (calcium and phosphate) to a large degree.

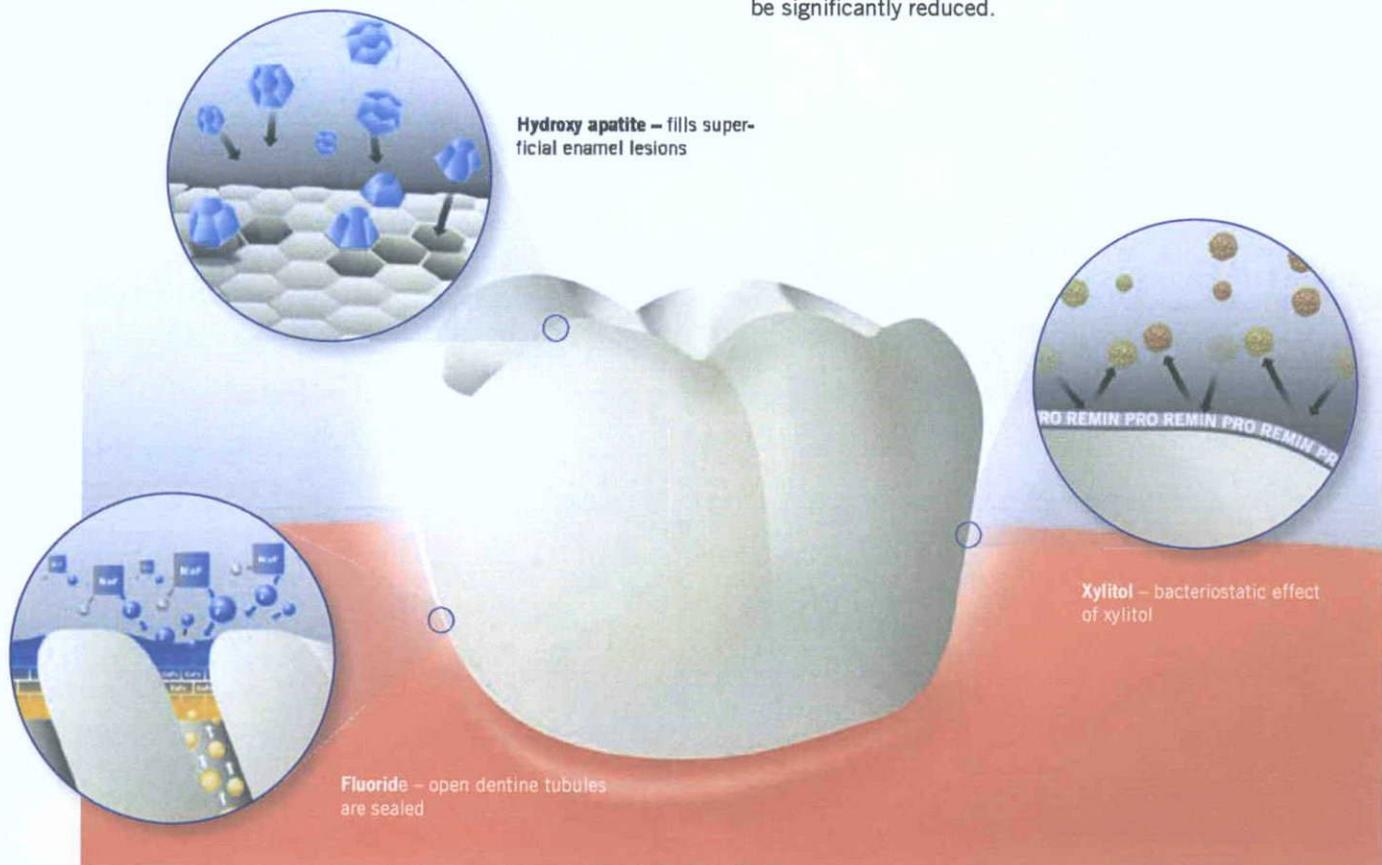
The hydroxy apatite contained in Remin Pro fills superficial enamel lesions and the tiniest irregularities that arise from erosion. Remin Pro adheres to the tooth substance and protects the tooth against demineralisation and erosion. The surface is noticeable smoothed, dentine tubules are superficially sealed. The smooth surface impairs the adhesion of bacterial plaque. The natural remineralisation is simultaneously promoted and the tooth thereby reinforced.

Fluoride

Fluoride is the proven agent for caries prophylaxis. Fluoride in conjunction with saliva on the tooth surface is converted into stable and acid-resistant fluorapatite. The fluoride contained in Remin Pro strengthens the tooth and thus makes it more resistant to acid attacks.

Xylitol

The sugar substitute xylitol is known for its cariostatic properties. Xylitol cannot be converted from cariogenic bacteria (unlike saccharose, for example) into the harmful metabolite lactic acid. Remin Pro also contains xylitol, so that the harmful effect of these bacteria and/or lactic acid, the metabolite, can be significantly reduced.



Salivation stimulation

Remin Pro is available in the flavours of mint, melon and strawberry. The nature-identical flavours in Remin Pro stimulate salivation. Natural remineralisation is thus promoted and the acidic environment neutralised.

Remin Pro after professional cleaning

Professional cleaning and the subsequent fluoridation are fixed components of effective caries prophylaxis. Remin Pro can be used as the conclusion to the preceding prophylaxis treatment, it immediately provides a noticeably pleasant feeling in the patient's mouth.

Remin Pro after whitening

Hypersensitivities are a familiar problem within the scope of tooth whitening, both in the surgery and at home. These can be caused by open dentine tubules, they can also be the cause of dehydration within the tooth's substance.

After treatment, Remin Pro is the ideal product in the treatment chain to restore the water balance in the tooth.

Remin Pro during orthodontic treatments

Since many areas are difficult to reach with the toothbrush during orthodontic treatments, there is an especially high risk of erosion and demineralisation. The concept behind Remin Pro's consistency is that even inaccessible areas are also optimally wetted. Areas under the bands and the brackets are effectively covered by the cream, so that there is effective protection for the preferential spots.

Smooth surfaces with Remin Pro

The smoothing and tooth substance filling effect of Remin Pro is visible on these SEM micrographs. Cervical dentine after an acid attack from orange juice can be seen as an example in the first picture. The second picture shows the result of a single treatment with Remin Pro. The dentine tubules are sealed to a large degree and the surface is visibly smoothed.

Visible smooth surfaces and sealed dentine tubules



Remin Pro

IDEAL FOR USE AT HOME

Remin Pro is the ideal product to continue the maintenance of dental health at home. The patient can very easily apply Remin Pro with a toothbrush, a finger or an individual splint after evening oral hygiene.

Indications

- After whitening
- After professional cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatments

Advantages

- Restores the mineral balance
- Neutralises the acids in plaque
- Fluoride for strengthening the tooth enamel
- Regenerates the tooth after whitening
- Regenerates the tooth after professional cleaning or restoration



Presentation

- REF 2007 3 tubes (1 each x 40 g melon, mint and strawberry)
- REF 2006 12 tubes mixed (4 each x 40 g \ melon, mint and strawberry)
- REF 2003 melon 12 tubes
- REF 2004 mint 12 tubes
- REF 2005 strawberry 12 tubes

VOCO GmbH
P.O. Box 767
27457 Cuxhaven
Germany
Tel.: +49 (0) 4721-719-0
Fax: +49 (0) 4721-719-140
info@voco.de
www.voco.com

Available from:

COVER SHEET MEMORANDUM

From: Reviewer Name

Mary Broue

Subject: 510(k) Number

K10104/SF

To: The Record

SE

Please list CTS decision code _____

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

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

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)		<input checked="" type="checkbox"/>
Nanotechnology		<input type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

Regulation Number 872.6030 Class* CL. I Product Code 76EJR

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [Signature] DS03 10/20/10
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 10/21/2010
(Division Director) (Date)



COVER SHEET MEMORANDUM

From: Reviewer Name: M. B. Zome
Subject: 510(k) Number: K101104
To: The Record

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

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

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.

Regulation Number

Class*

Product Code

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Ken Muly for MRE DEB 6/8/10
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 10/21/2010
(Division Director) (Date)

Browne, Myra E.

From: Browne, Myra E.
Sent: Tuesday, June 08, 2010 12:09 PM
To: 'mth.plaumann@voco.de'
Subject: K101104

Dear Mr. Plaumann,

(b) (4)



I have placed your document on hold until you submit the above deficiencies to the Document Mail Center.

If you have any questions, please feel free to contact my office.

Sincerely,
Myra Browne

Myra E. Browne, M.S.
Biologist
FDA
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-Rm. 2610
Silver Spring, MD. 20993
301-796-6278
myra.browne@fda.hhs.gov

Kim Hardy
6/8/10



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

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

K101104

Date: October 15, 2010
To: The Record
From: Myra E. Browne, M.S., Biologist
Office/Division: ODE/DAGID
510(k) Holder: Voco GmbH
Device Name: Voco Paste
Contact: Mr. Thorsten Gerkenmeier
Phone: 49-4721-719-200
Fax: 49-4721-719-109
Email: t.gerkenmeier@voco.de

Purpose and Submission Summary

The 510(k) holder would like to introduce Voco Paste into interstate commerce.

Voco Paste is an oral cavity abrasive polishing paste used to professionally clean and polish teeth.

Voco Paste is substantially equivalent (SE) to legally marketed oral cavity abrasive polishing pastes because the information submitted by Voco GmbH, demonstrates that the device has the same indication and technological characteristics as legally marketed oral cavity abrasive polishing pastes.

Administrative Requirements

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

Indications for Use

Voco Paste is intended to be used for the professional cleaning and polishing of teeth

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following dental procedures (i.e. professional tooth whitening) to prevent hypersensitivity.

The indication of Voco Paste does not differ from that of legally marketed oral cavity abrasive polishing paste.

Device Description/Formulation

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

The purpose of this 510(K) is to introduce a new product to market. No novel features have been introduced.

Voco Paste is a prophylactic paste indicated for use after various dental treatments (i.e. professional tooth whitening) to help prevent hypersensitivity. Voco Paste is a water-based cream that contains hydroxylapatite and fluoride. Voco Paste is available in three different flavors (melon, strawberry and mint). Voco Paste is packaged in the following two forms: a 40g tube or 50x2.5g foil pouches. Both packaging forms are available in all 3 flavors.

In the original submission, this product's name was Remin Pro. I informed the company that they needed to change the name of the product because "Remin Pro" implied that the prophylactic paste promotes remineralization. The company agreed to change the product name to Voco Paste. In addition, Voco is making no claim for remineralization.

The chemical composition of Voco Paste is as follows:



The company submitted fluoride release data for the fluoride content in chemical composition.

Contact History

The reviewer contacted the submitter by emails on June 8 and 30, and October 13, 2010, to request the name change of the product; revise the 510(k) summary; removal of all claims for the neutralization and remineralization of Voco Paste; and removal or translation of all items submitted in German only. The sponsor submitted the requested on September 29, 2010.

Deficiencies

No deficiencies have been identified.

Labeling

The labeling of Voco Paste has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.801.109. No unsubstantiated claims are purported.

Sterilization/Shelf Life/Reuse:

Voco Paste will be provided non-sterile and is not intended to be sterilized before use.

Biocompatibility

The formulation of Voco Paste includes no new components. This basic formulation is known to be biocompatible for this intended use. Thus, biocompatibility data is not required.

Software

Voco Paste contains no software.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Voco Paste is not a mechanical or electrical device. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing - Bench

Engineering performance test results are provided in Section III, Device Comparison.

Performance Testing - Animal

Animal test results were not provided for Voco Paste. This type of information is not needed for the assessment of safety and effectiveness of this product.

Performance Testing - Clinical

Human test results were not provided for Voco Paste. This type of information is not needed for the assessment of safety and effectiveness of this product.

Device Comparison

Predicate Device: GC MI Paste Plus (K070854) of GC America, Inc.

Physical Property	Voco Paste	GC MI Paste Plus (K070854)
Shear thinning (viscosity)	3800 Pa	2500 Pa
pH value	7.2	7.0
Density	1.05 g/ml	1.02 g/ml
Particle (grit) size	5 micrometer	5 micrometer

Voco Paste is comparable to other legally marketed oral cavity abrasive polishing pastes on the market, especially GC MI Paste Plus (K070854) product from GC America, Inc. These devices essentially have the same composition and physical properties. The difference in Voco Paste lies in the selection and relative percentages of its components, most of which have been found in legally marketed prophylaxis pastes. Voco Paste has in its chemical composition hydroxylapatite for occluding dentinal tubules to prevent hypersensitivity. The predicate product GC MI Paste Plus has in its chemical composition calcium phosphate/ACP. Neither product makes a claim for remineralization. Voco Paste, then, is a reconfiguration of an existing formulation.

The physical properties of Voco Paste appear to be adequate for its intended use.

No new technological characteristics have been introduced in Voco Paste that could affect its safety or effectiveness.

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Substantial Equivalence Discussion

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

Recommendation

Regulation Number: 872.6030
 Regulation Name: Oral Cavity Polishing Agent
 Regulatory Class: Class I
 Product Code: EJR

Myra E. Browne
 Myra E. Browne, M.S., Biologist
 Reviewer

10/19/10
 Date

Susan Runner
 M. Susan Runner, DDS
 Branch Chief

10/20/10
 Date

Browne, Myra E.

From: Thorsten Gerkensteiner [t.gerkensteiner@voco.de]
Sent: Monday, October 18, 2010 4:24 AM
To: Browne, Myra E.
Subject: Re: Voco Paste

Dear Mrs. Brown,

This is no problem: the mean particle diameter of the apatit filler in VOCO Paste is 5 µm.

Kind Regards

Thorsten Gerkensteiner

VOCO GmbH
P.O.B./Postfach 767
27457 Cuxhaven (Germany)
Telefon: +49 (0) 4721-719-200
Telefax: +49 (0) 4721-719-219
Internet: <http://www.voco.de>
<http://www.voco.com>
e-mail: t.gerkensteiner@voco.de

Geschäftsführer: Manfred Plaumann, Manfred Thomas Plaumann, Olaf Sauerbier
Amtsgericht Tostedt HRB 110134

RECHTSHINWEIS:

Diese E-Mail enthält vertrauliche Informationen, die nur für den o.g. Empfänger bestimmt sind!
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Original Message

processed by David.fx

Subject: Voco Paste (15-Okt-2010 19:25)
From: Browne, Myra E. <Myra.Browne@fda.hhs.gov>
To: t.gerkensteiner@voco.de

Dear Mr. Gerkensteiner,

Do you have the grit particle size for Voco Paste. If you can send me this information I need it to finalize your document.

Sincerely,
Myra Browne

Myra E. Browne, M.S.
Biologist
FDA
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-Rm. 2610
Silver Spring, MD. 20993

Browne, Myra E.

From: Thorsten Gerkenmeier [t.gerkenmeier@voco.de]
Sent: Thursday, October 14, 2010 4:14 AM
To: Browne, Myra E.
Subject: Re: K101104

Dear Mrs. Browne,

please find the requested information below:

VOCO Paste contains the sweetener

Xylitol (CAS No. 87-99-0)

and the white pigment

titanium dioxide (CAS No. 13463-67-7)

Although not primarily added as a pigment, the ingredient apatit (tricalcium diphosphate, CAS 7758-87-4) contributes to the opaque appearance of the VOCO Paste.

Just let me know, if there is any further information required.

Best Regards

Thorsten Gerkenmeier
Reg. Aff.

VOCO GmbH
P.O.B./Postfach 767
27457 Cuxhaven (Germany)
Telefon: +49 (0) 4721-719-200
Telefax: +49 (0) 4721-719-219
Internet: <http://www.voco.de>
<http://www.voco.com>
e-mail: t.gerkenmeier@voco.de

Geschäftsführer: Manfred Plaumann, Manfred Thomas Plaumann, Olaf Sauerbier
Amtsgericht Tostedt HRB 110134

RECHTSHINWEIS:
Diese E-Mail enthält vertrauliche Informationen, die nur für den o.g. Empfänger bestimmt sind!
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If you are not the intended recipient, then please notify us immediately by returning it to the originator.

Original Message

processed by David.fx

Subject: K101104 (13-Okt-2010 19:00)
From: [Browne, Myra E. <Myra.Browne@fda.hhs.gov>](mailto:Myra.Browne@fda.hhs.gov)
To: t.gerkenmeier@voco.de

Dear Mr. Gerkenmeier,

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In order to complete my review for Voco Paste I need you to identify the sweetener and the pigments in the chemical composition.

You can email these chemicals to me. Please let me know if you can send these by Friday, October 15. If they are not received by then, I will place the document on hold.

Sincerely,
Myra Browne

Myra E. Browne, M.S.
Biologist
FDA
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-Rm. 2610
Silver Spring, MD. 20993
301-796-6278
myra.browne@fda.hhs.gov

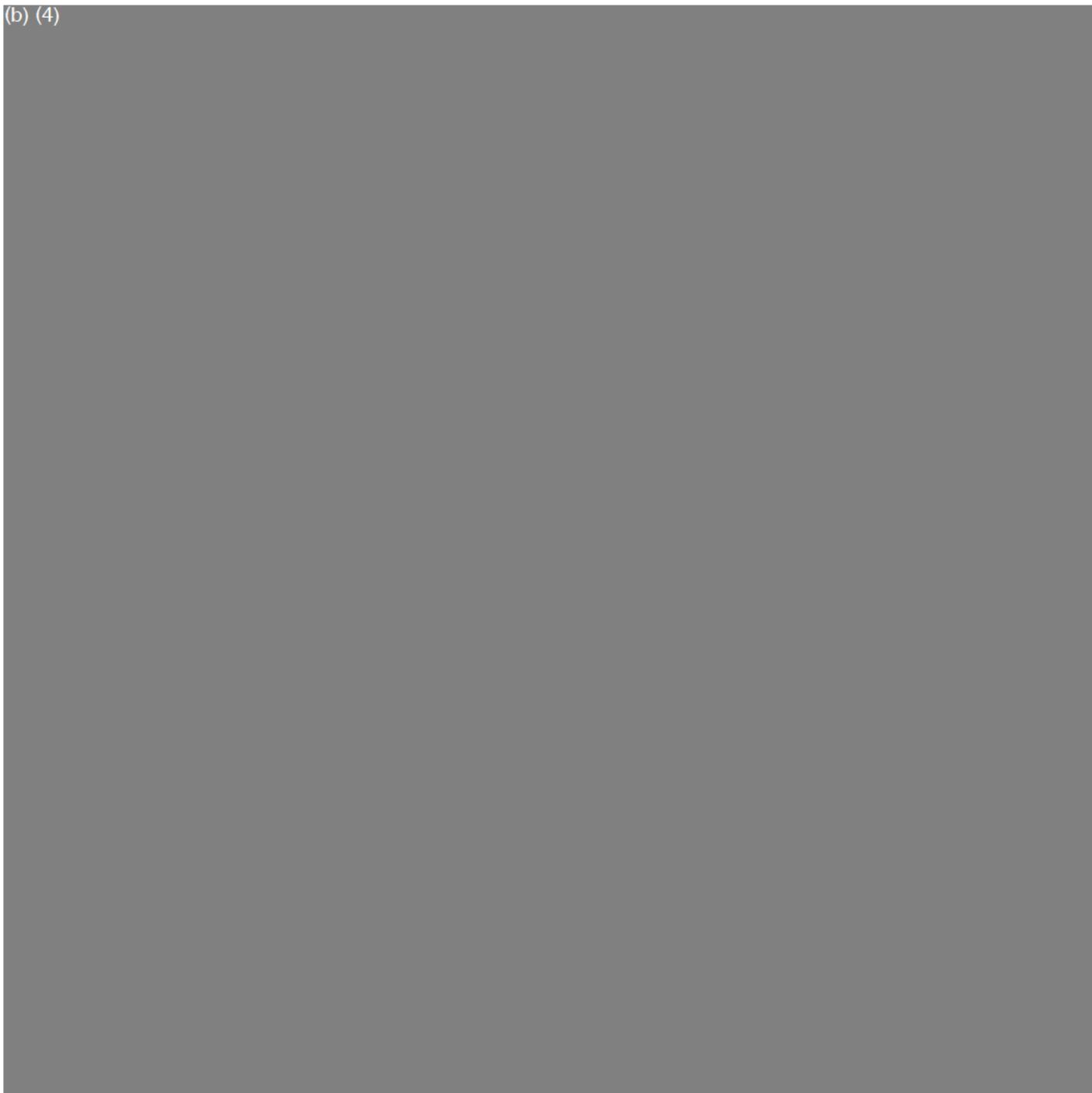
Browne, Myra E.

From: Browne, Myra E.
Sent: Wednesday, June 30, 2010 12:22 PM
To: 'Thorsten Gerkenmeier'
Subject: RE: registrations

Dear Dr. Gerkenmeier,

I just tried to contact Mr. Plaumann by telephone but his office was already closed for the day. I just want to let you know that I am placing your device on hold again because the following deficiencies still remain:

(b) (4)



60

(b) (4)

Thank you for your cooperation in the matter. Please feel free to contact me after July 14.

Sincerely,
Myra Browne

Myra E. Browne, M.S.
Biologist
FDA
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-Rm. 2610
Silver Spring, MD. 20993
301-796-6278
myra.browne@fda.hhs.gov

From: Thorsten Gerkenmeier [mailto:t.gerkenmeier@voco.de]
Sent: Wednesday, June 30, 2010 4:16 AM
To: Browne, Myra E.
Subject: registrations

Dear Mrs. Browne,

our secretary informed me that You left a message referring to our submissions. The message was deleted too soon so I don't know what information You've requested. Can You please re-submit Your request via email since it is easier to follow up by our department?

By the way: Mr. M. Th. Plaumann (managing board) has been enlisted as contact person with the FDA. All FDA requests are usually forwarded by him to our department in order to take care of them. This works well as long as he is not on a business trip, vacation or sick leave.

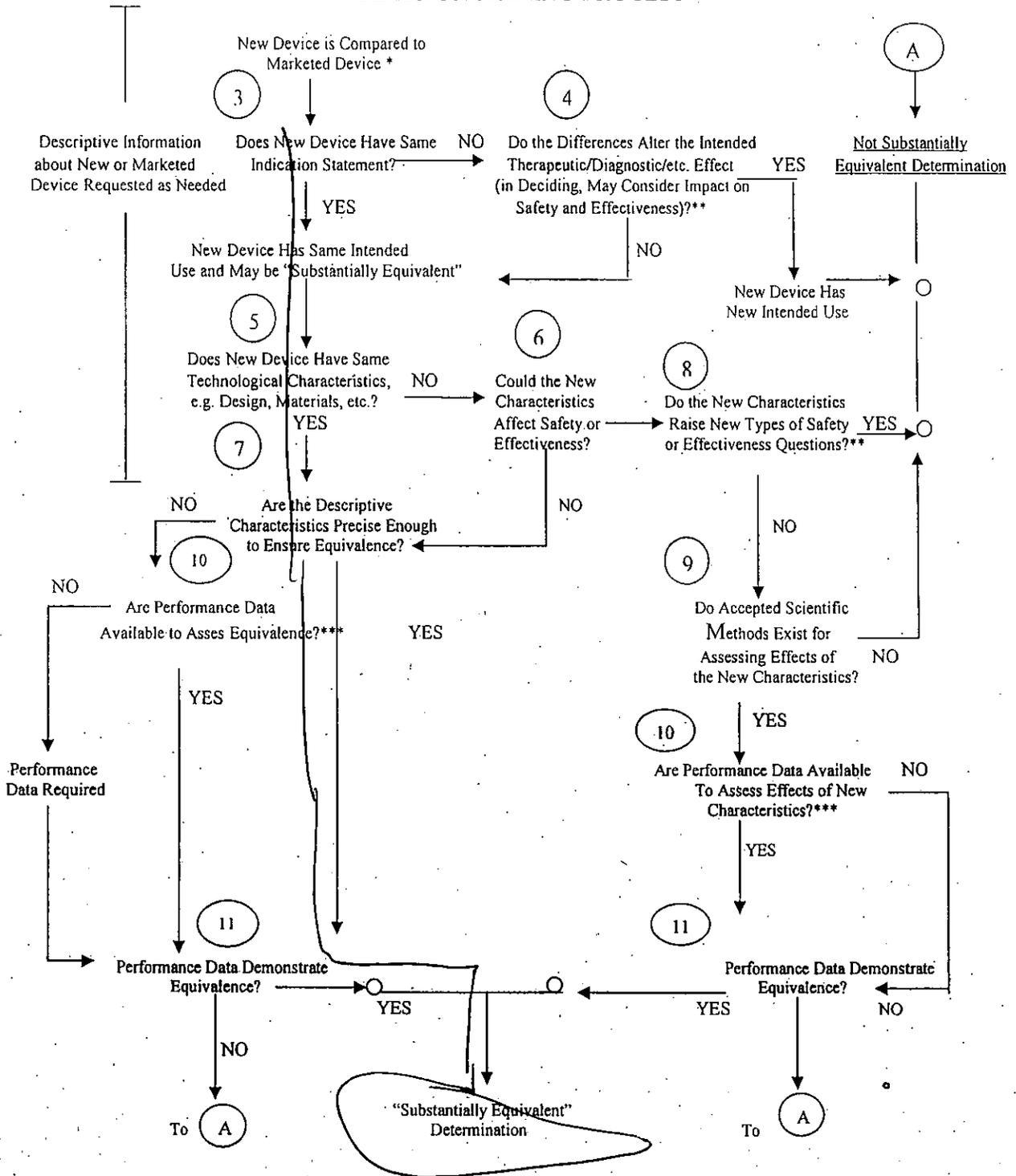
Is it possible to put Mrs. Fröhlich's and my own email address to the mailing list or do we have to be registered as official correspondents, too? If we (regulatory affairs dept.) receive the FDA requests directly then there is no delay in processing them.

Kind Regards

Thorsten Gerkenmeier

VOCO GmbH
P.O.B./Postfach 767
27457 Cuxhaven (Germany)

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



- ❖ 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ; WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 30, 2010

VOCO GMBH
ANTON-FLETTNER-STRASSE 1-3
CUXHAVEN
GERMANY D-27472
ATTN: M. TH PLAUMANN

510k Number: K101104

Product: REMIN PRO

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

VOCO GmbH • Postfach 767 • 27457 Cuxhaven • Germany

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue.

Silver Spring, MD 20993-0002
U. S. A.

VOCO

Anton-Flettner-Straße 1-3
27472 Cuxhaven

Tel.: +49 (0)4721-719-0
Fax: +49 (0)4721-719-109

info@voco.de
www.voco.de

FDA CDRH DMC
SEP 29 2010
Received

Dr. TG/KFr 27/09/2010

Re.: Traditional 510 (k) submission for the preparation VOCO Paste, K101104

Dear Mrs Browne,

Please find enclosed our revised documents for the above mentioned Medical Device.

In case of any questions or if you need additional documents, please feel free to contact the undersigning person by mail (t.gerkensmeier@voco.de) phone (+49-4721-719-200 or fax (+49-4721-719-219) for more information..

Many thanks for your help and cooperation,

with best regards
VOCO GmbH


Dr. Thorsten Gerkensmeier
(Regulatory Affairs)

Enclosures

K62

**Traditional 510(k) submission
for the preparation**

VOCO Paste

Research & Development

VOCO GmbH

Anton-Flettner-Str. 1-3, D-27472 Cuxhaven (Germany)

Tel.: +49-4721/719-0 FAX: +49-4721/719-109 e-mail: info@voco.de

Traditional 510(k) submission for the preparation VOCO Paste

Content:

Section 1	Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2	CDRH Premarket Review Submission Cover Sheet
Section 3	510(k) Cover Letter
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Section 7	Summary Report
Section 8	Device Description and Executive Summary
Section 9	Substantial Equivalence Discussion
Section 10	Proposed Labeling

Cuxhaven, dated April 14, 2010

VOCO GmbH



M.Th. Plaumann
(Managing Board)

Section 1

Medical Device User Fee Cover Sheet (Form FDA 3601)

Section 2

CDRH Premarket Review Submission Cover Sheet

Section 3

510(k) Cover Letter

Premarket Notification [510 (k)] Cover Letter

(April 14, 2010)

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

Subject: Traditional Premarket Notification Submission for the preparation
"VOCO Paste"

Submission according to "Guidance for Industry and FDA Staff"

Dear Sir:

This is to submit a traditional premarket notification submission pursuant to notifying the Food and Drug Administration that VOCO GmbH intends to introduce **VOCO Paste**, a paste for protection of oral hard tissue surfaces into U.S. interstate commerce for commercial distribution.

Confidentiality Statement

VOCO GmbH requests that the FDA disclose no specific product information, nor any administrative information regarding the progress of this marketing application, to anyone other than authorized FDA officers and employees, officers employed by VOCO GmbH, or the U.S. Designated Agent. Specific product information, such as its chemical composition, performance data or product performance data, is proprietary and not to be disclosed publicly without a written statement of approval by an officer of VOCO GmbH.

Establishment Registration Number

8010908

Device Trade Name

VOCO Paste

Device Classification

Agent, Polishing, Abrasive, Oral Cavity

Device CFR Section

21 CFR 872.6030

FDA Device Class

Class II (Special Controls)

FDA Product Code

EJR

Classification Panel

76 Dental

Device to which VOCO Paste is claimed Substantially Equivalent

GC MI Paste Plus, K070854, GC America

Device Indications

VOCO Paste is intended to be used after professional tooth whitening, professional tooth cleaning and for prevention and control of hypersensitivities.

Contact Information

If there are any questions you may contact Manfred Thomas Plaumann, Managing Board for VOCO GmbH by telephone at + 49 (4721) 719-200 or e-mail at mth.plaumann@voco.de

Section 4

Indications for Use Statement

Indications for Use Statement

510(k) Number: K 101104

Device Name: VOCO Paste

Indications for Use:

VOCO Paste is intended to be used after professional tooth whitening, professional tooth cleaning and for prevention and control of hypersensitivities.

Prescription Use X OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5

510(k) Statement

**PREMARKET NOTIFICATION
510(k) STATEMENT
(As Required By 21 CFR 807.93)**

I certify that, in my capacity as Managing Director of VOCO GmbH, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



(Signature of Certifier)

Mr. Manfred Thomas Plaumann

(Typed Name)

April 14, 2010

(Date)

(Premarket Notification [510(k)] Number)

Section 6

Truthful and Accurate Statement

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required By 21 CFR 807.87(k)]**

I certify that, in my capacity as the Managing Director of VOCO GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Manfred Thomas Plaumann (Managing Board)

(Typed Name)

April 14, 2010

(Date)

Premarket Notification [510(k)] Number

Section 7

Summary Report

- not applicable -

Section 8

Device Description and Executive Summary

Device Description and Executive Summary

VOCO Paste is a water-based cream that contains hydroxyl apatite and fluoride. **VOCO Paste** is available in the flavours: melon, strawberry and mint. **VOCO Paste** provides extra protection.

VOCO Paste will be offered in the following presentations:

- 40g tube available in mint, melon and strawberry
- 50x2.5g foil pouches in mint, melon and strawberry

VOCO Paste is intended for use as:

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

VOCO Paste is claimed to be substantially equivalent to **GC MI Paste Plus** (K070854, GC America)

a.1.

Applicant: VOCO GmbH, Anton-Flettner-Str. 1-3,
27472 Cuxhaven/Germany

Phone: +49 4721 719 0

Contact: M. Th. Plaumann

Date prepared: April 14, 2010

a.2.

Trade or proprietary name: **VOCO Paste**

Classification name: Agent, Polishing, Abrasive, Oral Cavity (872.6030)

a.3.

Predicate device: GC MI Paste Plus, K070854

a.4.

Device description:

VOCO Paste is a water-based cream that contains finely dispersed hydroxyl apatite. **VOCO Paste** provides extra protection for teeth.

a.5.

Intended use:

VOCO Paste is intended to be used after professional tooth whitening, professional tooth cleaning and for prevention and control of hypersensitivities.

a.6.

Technological characteristics:

VOCO Paste and the legally marketed device K070854 (**GC MI Paste Plus, GC America**) share the similar indications. The components of **VOCO Paste** serve the same purpose as the ingredients of the predicate device. The components of **VOCO Paste** cover materials for the dental hypersensitivity prevention and control.

We believe that the prior use of the components of **VOCO Paste** in legally marketed devices and the performance data and results provided support the safety and effectiveness of **VOCO Paste** for the intended use.

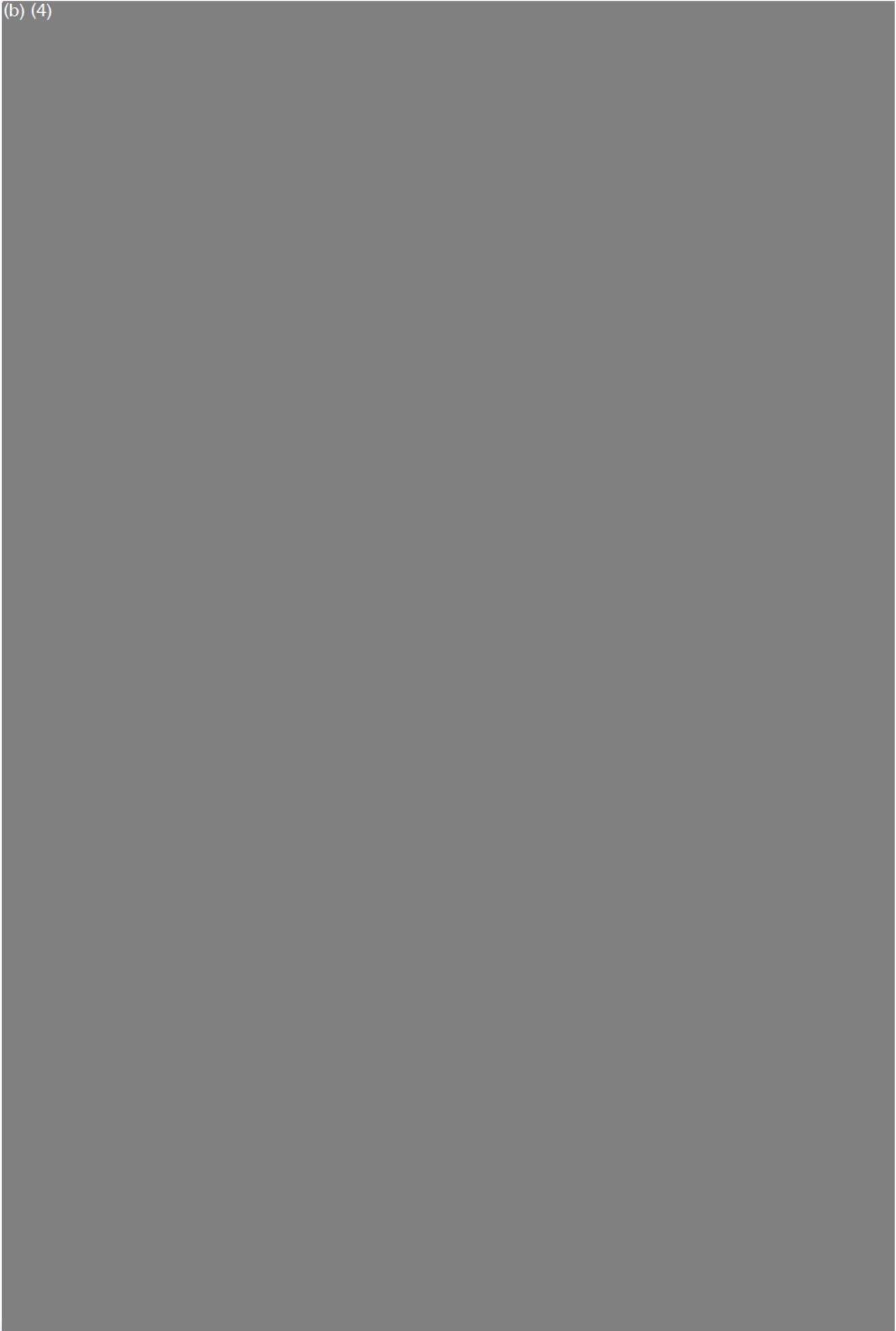
Compositional similarity of VOCO Paste and the predicate device GC MI Paste Plus

Both preparations serve the same purpose, thus, the components are functionally equivalent. The ingredients are chemically comparable as well featuring similar properties.

Function	Ingredient	VOCO Paste	GC MI Paste Plus
Inert Filler	Pigments	(b) (4)	
Stabilizer	Parabene	(b) (4)	
Matrix	Glycerine	(b) (4)	
	Water	(b) (4)	
	Propyleneglycol	(b) (4)	
Thickener	Carboxymethylcellulose	(b) (4)	
	Silica	(b) (4)	
Additives	Phosphoric acid.	(b) (4)	
	CPP-ACP	(b) (4)	
	Hydroxylapatite	(b) (4)	
	Sodium Fluoride	(b) (4)	
	Sweetener	(b) (4)	
	Flavors	(b) (4)	

The prior use of all of the components of **VOCO Paste** in legally marketed devices support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

(b) (4)



(b) (4)



b.2.

Clinical tests

Not applicable.

b.3.

Conclusions

VOCO Paste is similar to MI Paste with regard to composition and intended use. Both preparations are considered safe and effective for their intended use.

For details of product performance data please see section 9 (substantial equivalence comparison).

Section 9

Substantial Equivalence Comparison: Compositional similarity, Indications for Use and Product Performance Data

Subject device: **VOCO Paste**

Predicate devices: **GC MI Paste Plus** (K070854, GC America)

Basis for claiming substantial equivalence:

VOCO Paste is substantially equivalent to **GC MI Paste Plus** with respect to:

- intended use
- composition
- product performance

Similarity of intended use:

Indications for use	
VOCO Paste (subject device)	GC MI Paste Plus (predicate device)
<ul style="list-style-type: none">- following in-office bleaching procedures- after ultrasonic, hand scaling or root planing- following professional tooth cleaning- hypersensitivity prevention and control- during orthodontic treatment- for patients suffering from erosion, xerostomie or Sjögrens syndrome- for special needs adult patients	<ul style="list-style-type: none">- for patients who suffer from aggressive caries and loss of tooth structure, from dental erosion and accelerated tooth wear following head and neck radiotherapy- for pregnant women- during and/or after orthodontics- for patients with an acidic oral environment and gastric reflux- for patients with poor plaque control and high caries risk

Compositional similarity of VOCO Paste and the predicate device GC MI Paste Plus

Both preparations serve the same purpose, thus, the components are functionally equivalent. The ingredients are chemically comparable as well featuring similar properties.

Function	Ingredient	VOCO Paste	GC MI Paste Plus
Inert Filler	Pigments	(b) (4)	
Stabilizer	Parabene		
Matrix	Glycerine		
	Water		
	Propyleneglycol		
Thickener	Carboxymethylcellulose		
	Silica		
Additives	Phosphoric acid		
	CPP-ACP		
	Hydroxylapatite		
	Sodium Fluoride		
	Sweetener		
	Flavors		

The prior use of all of the components of **VOCO Paste** in legally marketed devices support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

Formulation of VOCO Paste:

(b) (4)



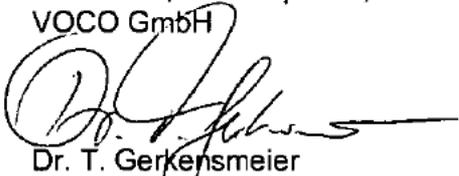
(b) (4)



(b) (4)



Cuxhaven, dated April 14, 2010
VOCO GmbH



Dr. T. Gerkenmeier
Scientific Dept.

(b) (4)



Section 10

Proposed Labeling

DEVICE LABELING PRESCRIPTION DEVICE CAUTION STATEMENT

In accordance with Title 21 Code of Federal Regulations (CFR) Part 801.109(b)(1), the label information for this device will clearly bear a Prescription Device Caution Statement, as follows:

"Caution: Federal laws restrict this device to sale by or on the order of a dentist."

**VOCO
Paste**
Protective dental care
with fluoride and hydroxy apatite
Schützende Zahnpflege
mit Fluorid und Hydroxylapatit

**VOCO
Paste**
Protective dental care
with fluoride and hydroxy apatite
Schützende Zahnpflege
mit Fluorid und Hydroxylapatit

FR Cette dentifrice est indiquée pour une utilisation en tant qu'hydroxyapatite. EE Cuidado dental protector con fluoruro y hidroxapatita. IT Protezione dentale con fluoro e idrossiapatite. NL Beschermende tandpasta met fluoride en hydroxylapatit. NO Beskyttende tannpasta med fluorid og hydroxylapatit. PL Pastka z fluoridem i hydroksyapatytem. PT Pasta dental com fluoreto e hidroxapatita. RO Pasta dentară cu fluor și hidroxapatită. RU Защитная зубная паста с фтором и гидроксиапатитом. SK Pastuška na chránenie zubov s fluoridom a hydroxylapatitom. SL Pastila za zaščito zobov s fluoridom in hidroksilapatitom. SV Skyddande tandpasta med fluorid och hydroxylapatit. TR Koruyucu diş macunu. UK Зубна паста з захисними компонентами фториду та гідроксиапатиту. US Fluoride and Hydroxyapatite Toothpaste. VI Bảo vệ răng với thành phần Fluor và Hydroxyapatit. ZN Zdravilna pasta za zob s fluoridom in hidroksilapatitom. CE Conformité Européenne

Made in Germany
NET WT: 3 x 40 g



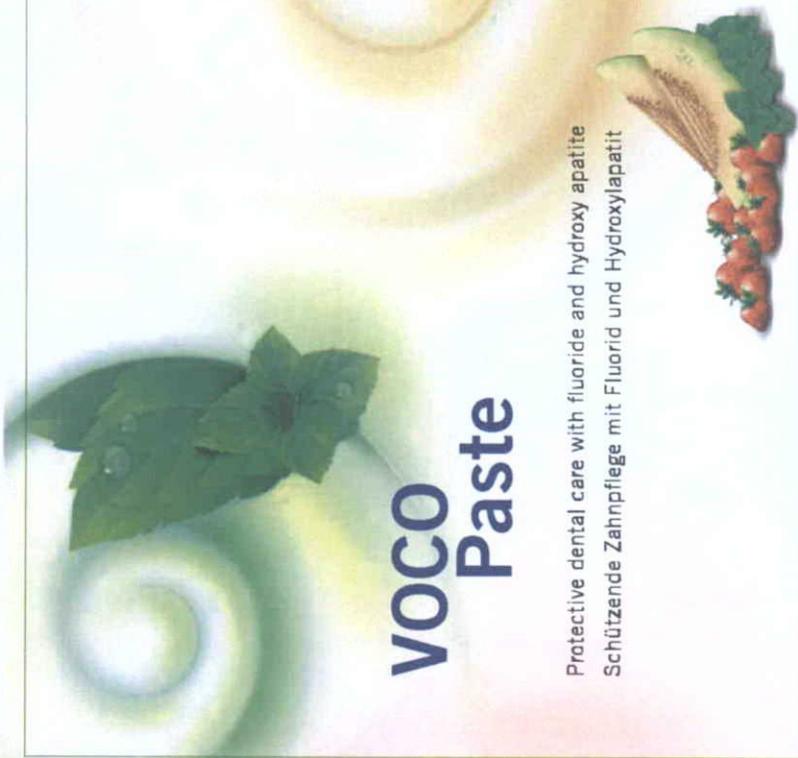
Protective dental care with fluoride and hydroxy apatite
Schützende Zahnpflege mit Fluorid und Hydroxylapatit

VOCO

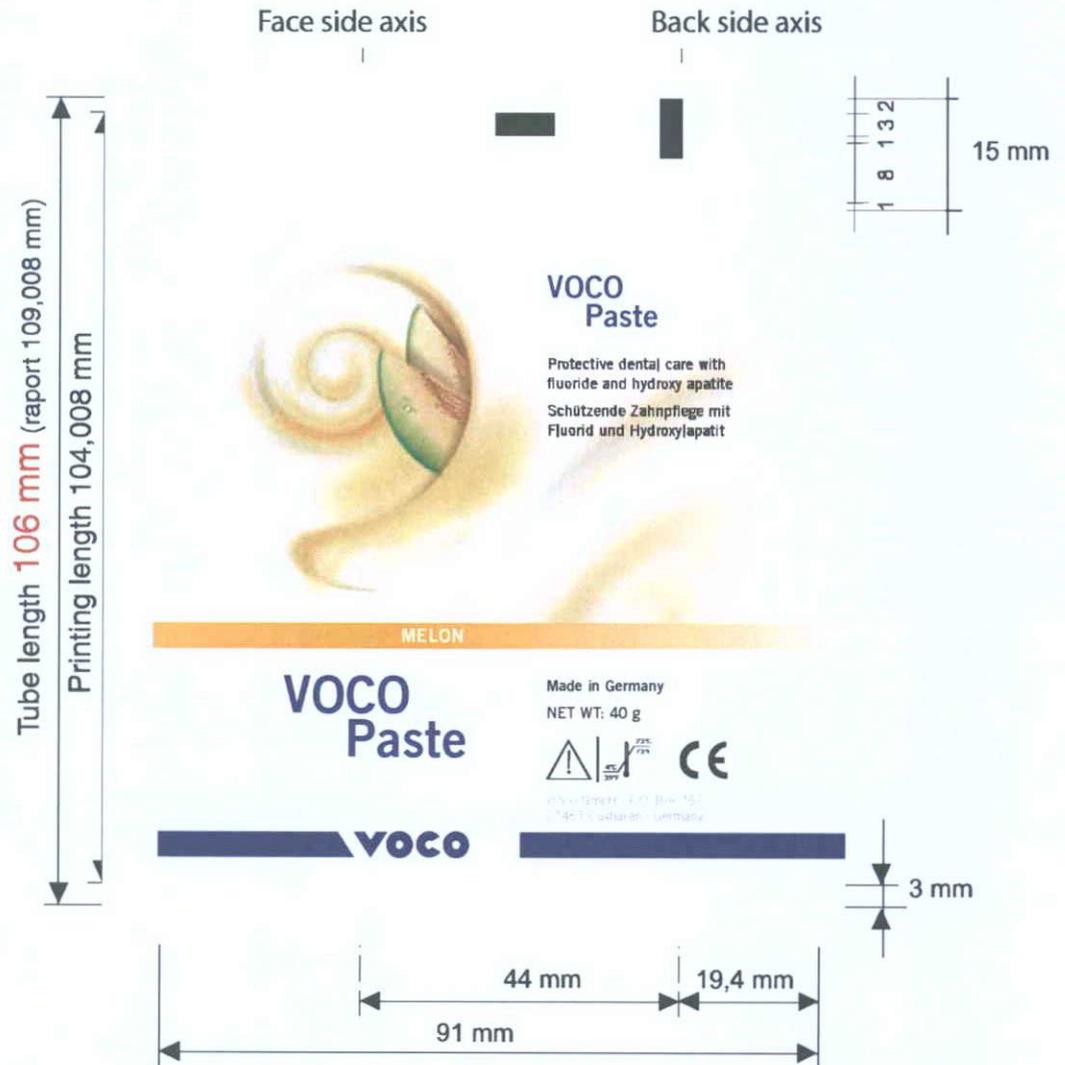
VOCO

© 2010 Voco GmbH, P.O. Box 767, 42687 Solingen, Germany

Important: Read instructions before use.
Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist. For dental use only.
Warnings: Avoid contact with eyes and skin. If contact occurs, flush immediately with plenty of water and consult a physician. Keep out of reach of children and do not store together with food.



**VOCO
Paste**



 Laminate format \varnothing 28 mm (91 x 109,008 mm)

 Printing format (80 x 104,008mm)

Colours:

„Melon Yellow“

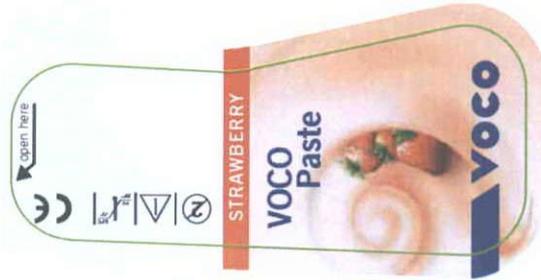
Cyan: 0%
Magenta: 30%
Yellow: 100%
Black: 0%

„VOCO Blue“

Cyan: 100%
Magenta: 80%
Yellow: 0%
Black: 20%







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VOCO Paste

Carefully read instructions prior to use

VOCO Paste is a water-based cream that contains hydroxy, apatite, and fluoride. VOCO Paste is available in the flavors: melon, strawberry, and mint. VOCO Paste provides extra protection for teeth and, in doing so, it helps neutralize acids in acid-forming bacteria in plaque. VOCO Paste additionally facilitates the neutralization of other acids in the mouth.

Indications:

- After tooth whitening
- After professional tooth cleaning
- For the prevention and control of hypersensitivities
- During orthodontic treatment

Application:

1. Apply a pea-size amount of VOCO Paste to the tooth with a finger or suitable instrument (toothbrush or swab) and distribute.
2. The patient should distribute the remaining VOCO Paste in his or her mouth for with the tongue. VOCO Paste and the saliva should remain in the mouth for as long as possible (minimum of 3 minutes) for an optimal result.
3. The patient should spit out the remaining amount. Rinsing should be avoided if possible. The patient should wait at least 30 minutes after the treatment before eating or drinking.

Storage:

Store VOCO Paste in a cool, dry area protected from direct sunlight (39° F - 73° F (4° C - 23° C)). Do not use the material after the expiry date.

Precautions:

1. Always close the tube immediately after use.
2. VOCO Paste contains parabens, fluoride and hydroxyapatite (calcium and phosphate). Do not use in cases of known allergies to any of the ingredients.
3. The application of VOCO Paste is not recommended for patients under 6 years of age for home use on children under 12 years.
4. In case of contact with the eyes, flush thoroughly with plenty of water and seek medical attention.
5. Immediately discontinue treatment and seek medical attention if symptoms of angioedema occur that can be attributed to the ingredients in VOCO Paste.

This material has been developed solely for use in dentistry. Processing should be done strictly according to the instructions for use. VOCO recognizes its responsibility to replace products if proven to be defective. VOCO does not accept any liability for damage or loss, directly or indirectly, stemming from the use or inability to use the product. VOCO does not accept any liability for the responsibility of the user to determine the suitability of the use of its product. Descriptions and data constitute no warranty of attributes and are not binding. CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a dentist.

No person is authorized to provide any information which deviates from the information provided in the instructions for use.

For questions or comments, please call 1-888-658-2584.

Keep this material out of reach of children.

For dental use only. Manufactured by:

VOCO GmbH Phone +49 (4721) 718-0 P.O. Box 787 Fax +49 (4721) 718-140 D-487 Cullowen e-mail: marketing@voco.com Germany www.voco.com

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VOCO Paste

Leer esmeradamente las instrucciones antes del uso

VOCO Paste es una crema de base acuosa que contiene hidroxiapatita y fluoruro. VOCO Paste está disponible en los sabores: melón, fresa y menta. VOCO Paste proporciona una protección extra para los dientes y ayuda a reducir los ácidos en bacterias acidogénicas en la placa dental. VOCO Paste colabora también en la neutralización de otros ácidos en la boca.

Indicaciones:

- Después del blanqueamiento
- Después de la limpieza dental profesional
- Prevención y control de hipersensibilidades
- Durante un tratamiento ortodóncico

Aplicación:

1. Aplicar VOCO Paste - en cantidad de una alubia - con el dedo o un instrumento apropiado (cepillo o goteador) en los dientes y distribuir.
2. El VOCO Paste restante debe ser distribuido con la lengua en la boca; para un resultado óptimo deberían permanecer VOCO Paste y la saliva el mayor tiempo posible en la boca (por lo menos 3 minutos).
3. Salivar los restos; de ser posible se debería evitar un enjuague. El paciente debería comer o beber no menos de 30 minutos después del tratamiento.

También para el uso doméstico después de limpiar los dientes.

Conservación:

Conservar en un lugar fresco y seco, protegido de la luz directa del sol (39° F - 73° F (4° C - 23° C)). El material no se debe utilizar después de la fecha de caducidad.

Precauciones:

1. Cerrar el tubo inmediatamente después del uso.
2. Contiene parabens, flúor e hidroxiapatita (calcio y fósforo). No usar en caso de alergia contra estos componentes.
3. No se recomienda el uso en pacientes menores a 6 años así como el uso de este producto con los ojos; lavar inmediatamente con agua corriente y contactar a un médico.
4. En caso de contacto con los ojos, lavar inmediatamente con agua corriente y contactar a un médico.
5. En caso de que se presenten síntomas de un angioedema que se podría imputar a los componentes de VOCO Paste, se debería interrumpir inmediatamente el tratamiento y contactar a un médico.

Este material se desarrolló exclusivamente para el uso del odontólogo. El proceso debe ser como está indicado en la información de uso. VOCO reconoce su responsabilidad de reemplazar los productos si se muestran que están defectuosos. VOCO no acepta la responsabilidad de cualquier perjuicio o pérdida que descienda del uso o de la incapacidad de usar los productos descritos. Antes de usarlo, es la responsabilidad del usuario de determinar lo adecuado del producto para su uso intencional. El usuario supone todo el riesgo y la responsabilidad en conexión con eso. Descripciones y datos no constituyen ninguna garantía y no son aglutinantes.

ATENCIÓN: La legislación americana restringe este dispositivo para venderlo o el pedido del dentista.

Ninguna persona está autorizada de proveer ninguna información que desvíe de las informaciones provistas en estas instrucciones de uso.

Para preguntas o comentarios, por favor, llamen al 1-888-658-2584.

Manténgase fuera del alcance de los niños.

Sólo para uso dental.

Fabricado por:

VOCO GmbH Phone +49 (4721) 718-0 P.O. Box 787 Fax +49 (4721) 718-140 D-487 Cullowen e-mail: marketing@voco.com Germany www.voco.com



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Handwritten mark