DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 11, 2016

3M Deutschland GmbH
Dr. Desi W. Soegiarto
Group Leader Regulatory Affairs Medical Devices
ESPE Platz
Seefeld, Bavaria 82234
GERMANY

Re: K151748
Trade/Device Name: Clean & More
Regulation Number: 21 CFR 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: PIP
Dated: January 15, 2016
Received: January 19, 2016

Dear Dr. Soegiarto:

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.

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 contact 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. 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K151748

Device Name
Clean & More

Indications for Use *(Describe)*

- Professional cleaning of teeth: Removal of subgingival and supragingival plaque-biofilm and stains
- Professional cleaning of teeth including patients with dentin hypersensitivity
- Treatment of dentin hypersensitivity by blockage of the dentin tubules
- Can also be used in the presence of fixed orthodontic devices (brackets), restorative and prosthetic materials, and implants
- For maintenance in periodontitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth
- For maintenance in periimplantitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss
Germany

Postal Address:
ESPE Platz
82229 Seefeld
Germany

☎+49 (0)8152 700-0
🖷+49 (0)8152 700-1366
Internet: www.3MESPE.com
E-Mail: info3MESPE@3M.com
WEEE-Reg.-Nr. DE 36963167
VAT-ID: DE 120679179

510(k) SUMMARY: K151748

Submitter

Company: ..... 3M Deutschland GmbH
Street: ..... ESPE Platz
ZIP-Code, City: ..... D-82229 Seefeld
Federal State: ..... Bavaria
Country: ..... Germany
Establishment Registration Number 9611385
Official Correspondent & Contact: ..... Dr. Desi W. Soegiarto,
..... Regulatory Affairs
Phone:..... +49-8152-700 1169
Fax:..... +49-8152-700 1869
E-mail:..... desi.soegiarto@mmm.com
Date: ..... March 5, 2016

Name of Device

Proprietary Name: ..... Clean & More

Product Code: ..... PIP

Common Name: ..... Prophy Powder, Airbrush Accessory

Regulation Number: ..... 21 CFR 872.6080

Predicate Devices

Primary Predicate Device

Clinpro Prophy Powder K140684
..... by 3M Deutschland GmbH, Germany

Product Code: ..... PIP

Common Name: ..... Prophy Powder, Airbrush Accessory

Regulation Number: ..... 21 CFR 872.6080

Reference Device 1

OSspray Cleaning Compound K062502
..... by OSspray Ltd. – London, U.K.

Product Code: ..... EJR

Common Name: ..... Prophy Powder, Airbrush Accessory

Regulation Number: ..... 21 CFR 872.6030

Reference Device 2

Vanish Varnish, 5% Sodium Fluoride White Varnish K092141
..... by 3M ESPE Dental, St. Paul, MN - USA

Product Code: ..... LBH

Common Name: ..... Dental Varnish

Regulation Number: ..... 21 CFR 872.3260

Device Description

Clean & More is classified as airbrush (21 C.F.R. § 872.6080) because it is a powder to be used with air polishing devices in the professional tooth cleaning.

Clean & More is a prophylactic powder for gentle and professional sub- and supragingival cleaning of teeth, including the removal of plaque-biofilm and stains, using commercially available air polishing devices.

Clean & More is a glycine based air polishing powder containing functionalized tri-calcium phosphate, a substance which blocks open dentin tubules on the tooth surface, thereby contributing to a reduction in dentin hypersensitivity.

Indications for Use

• Professional cleaning of teeth: Removal of subgingival and supragingival plaque-biofilm and stains

• Professional cleaning of teeth including patients with dentin hypersensitivity

• Treatment of dentin hypersensitivity by blockage of the dentin tubules

• Can also be used in the presence of fixed orthodontic devices (brackets), restorative and prosthetic materials, and implants

• For maintenance in periodontitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth

• For maintenance in periimplantitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth

Comparison

Chemical composition, performance, fundamental technology, and intended use of Clean & More have been compared to the predicate devices.

As Clinpro Prophy Powder (K140684, 3M Deutschland GmbH, Germany) and OSspray Cleaning Compound (K062502, OSspray Ltd, London, U.K.), Clean & More is an air polishing powder to be used with air polishing devices in the professional tooth cleaning. Whereas OSspray Cleaning Compound is composed of calcium phosphosilicate compound in powder form, Clean & More and Clinpro Prophy Powder consist of water-soluble amino acid glycine. Like OSspray Cleaning Compound and Vanish Varnish (K092141, by 3M ESPE Dental, USA), Clean & More contains chemical component to block dentin tubules in order to reduce dentinal hypersensitivity.

Comparative testing, both *in vitro* and *in vivo*, revealed equivalent results in performance of Clean & More and the predicate device.

The tables below summarize the basic composition, fundamental technology, and intended use of Clean & More and predicate devices:

Tab. Substantial equivalence: Comparison of basic composition and fundamental technology

Clean & More	**Clinpro Prophy Powder**	**OSspray Cleaning Compound**	**Vanish Varnish, 5% Sodium Fluoride White Varnish**
Subject Device	**Primary Predicate Device**	**Reference Predicate Device 1**	**Reference Predicate Device 2**
K151748	**K140684**	**K062502**	**K092141**
Basic Composition			
Glycine based prophy powder containing functionalized tricalcium phosphate	Glycine based prophy powder	Calcium phosphosilicate compound in powder form	Varnish containing sodium fluoride and functionalized tricalcium phosphate
Fundamental Technology			
Dental prophypalxis powder, dentin tubule occlusion	Dental prophypalxis powder	Dental prophypalxis powder, dentin tubule occlusion	Cavity varnish, dentin tubule occlusion

Tab. Substantial equivalence: Comparison of Indications for Use (1

Clean & More	**Clinpro Prophy Powder**	**OSspray Cleaning Compound**	**Vanish Varnish, 5% Sodium Fluoride White Varnish**
Subject Device	**Primary Predicate Device**	**Reference Predicate Device 1**	**Reference Predicate Device 2**
K151748	**K140684**	**K062502**	**K092141**
Indications for Use (1) / Principle of operation: Cleaning			
• Professional cleaning of teeth: Removal of subgingival and supragingival plaque-biofilm and stains • Professional cleaning of teeth including patients with dentin hypersensitivity • Can also be used in the presence of fixed orthodontic devices (brackets), restorative and prosthetic materials, and implants • For maintenance in periodontitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth • For maintenance in periimplantitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth	• Professional cleaning of teeth: Removal of subgingival and supragingival plaque-biofilm and stains • Can also be used in the presence of fixed orthodontic devices (brackets), restorative and prosthetic materials, and implants • For maintenance in periodontitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth • For maintenance in periimplantitis therapy after completion of initial treatment - when using standard devices - for gingival pockets up to 5 mm in depth	The OSspray Cleaning Compound is intended for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment.	---

Tab. Substantial equivalence: Comparison of Indications for Use (2

Clean & More	**Clinpro Prophy Powder**	**OSspray Cleaning Compound**	**Vanish Varnish, 5% Sodium Fluoride White Varnish**
Subject Device	**Primary Predicate Device**	**Reference Predicate Device 1**	**Reference Predicate Device 2**
K151748	**K140684**	**K062502**	**K092141**
Indications for Use (2) / Principle of operation: Mechanical occlusion of dentin tubuli			
• Treatment of dentin hypersensitivity by blockage of the dentin tubules	---	The OSspray Cleaning Compound is also intended to provide relief from tooth sensitivity during the prophylaxis treatment.	Treatment of hypersensitive teeth Use on exposed dentin and root sensitivity

Performance Data: Non-clinical Performance Testing

In vitro testing was conducted to examine cleaning effect, plaque removal from bovine enamel, surface roughness of bovine enamel and composite materials, abrasion of bovine enamel and dentin, and removal of plaque-biofilm on zirconia and titanium surfaces comparing the performance of Clean & More to Clinpro Prophy Powder (K140684).

Standards: Not applicable. There are no standards specifically for prophy powders.

The cleaning effect of Clean & More is equal compared to Clinpro Prophy Powder air polishing powder.

Plaque removal from bovine enamel was very efficient with Clinpro Prophy Powder as well as Clean & More. Plaque removal efficiency of Clean & More is comparable to Clinpro Prophy Powder.

Statistical evaluation of the surface roughness data showed no difference in surface roughness of bovine enamel surface after cleaning with Clean & More and Clinpro Prophy Powder.

ANOVA evaluation of observations of composition materials after cleaning with Clean & More and after cleaning with Clinpro Prophy Powder revealed no statistically significant difference in surface roughness.

The abrasion of bovine enamel was minimally detectable for Clean & More and Clinpro Prophy Powder.

The abrasions of bovine dentin caused by Clean & More and Clinpro Prophy Powder were nearly as low as the abrasion on bovine enamel.

Keyence microscope observation revealed a gentle cleaning effect on enamel surface with Clean & More and Clinpro Prophy Powder.

Surface analysis of dentine showed no differences to enamel when using the glycine based air polishing powders: Clean & More and Clinpro Prophy Powder.

Tests have shown that plaque-biofilm removal on zircon and titanium surfaces with Clean & More was equivalent to treatment with Clinpro Prophy Powder.

Performance Data: Clinical Study

Effect of Clean & More for professional cleaning of teeth including patients with dentin hypersensitivity and treatment of dentin hypersensitivity has been shown in a Clinical study conducted according to ISO 14155:2011 – Good Clinical Practice (GCP). The objective of the study was to determine pain level during treatment with subsequent reduction of hypersensitivity, and the sustainability of the effect. A total of 40 subjects were enrolled with predetermined hypersensitivity on at least two teeth determined by air blast and tactile scoring. After providing the Clean & More treatment the incidence and degree of dentinal hypersensitivity was again determined after treatment, at 10 days, 4 weeks and 3 and 6 months. Treatment with Clean & More resulted in statistically significant hypersensitivity relief based on tactile stimuli at 10 days and up to 4 weeks.

Performance Data: Biocompatibility Testing

The biocompatibility of Clean & More has been assessed by a board-certified toxicologist according to recommendations in FDA guidance and internationally recognized standards for medical and dental devices.

The biocompatibility assessment for this product was conducted in accordance with the following Guidance:
l) Testing guidelines outlined in the FDA General Program Memorandum G95.
2) ISO 10993-1:2009(E) Biological evaluation of medical devices - Part I: Evaluation and testing within a risk management process; in addition, relevant detailed guidance in ISO Standards I 0993-3:2003 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993-5:2009 (Tests for in vitro cytotoxicity), 10993-10:2010 (Tests for irritation and skin sensitization); and l 0993-11:2006 (Tests for systemic toxicity) was considered;
3) ISO 7405:2008 Dentistry -- Evaluation of Biocompatibility of Medical Devices in Dentistry;

Conclusions

Performance test results from comparative *in vitro* testing together with results from comparative clinical testing to evaluate reduction in dental hypersensitivity after cleaning using Clean and More and Clinpro Prophy Powder, demonstrate that Clean and More blocks dentin tubules, cleans tooth surfaces and provides relief for patients suffering from dentinal hypersensitivity. The conclusion of the biocompatibility assessments is that Clean & More is safe for its intended use.

Substantial Equivalence Statement

The contents of this 510(k) premarket notification for Clean & More demonstrate substantial equivalence to the predicate devices for basic composition, fundamental technology, performance, and indications for use. Although the indications are not exactly identical to the predicates this new device incorporates the elements of the primary and reference predicates. Data has been presented for each of these indications. The data and clinical use supports that the inclusion of treatment of hypersensitivity during dental prophylaxis.