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

October 24, 2014

3M Deutschland Gmbh
Dr. Desi Soegiarto
Regulatory Affairs Specialist
ESPE Platz
Seefeld, D-D82229
GERMANY

Re: K140684
Trade/Device Name: Clinpro Prophy Powder
Regulation Number: 21 CFR 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: PIP
Dated: September 23, 2014
Received: September 25, 2014

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S
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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)*

K140684

Device Name
Clinpro™ Prophy Powder

Indications for Use *(Describe)*

• Removal of subgingival and supragingival plaque; can also be used in the presence of permanent orthodontic apparatus (brackets) and implants
• For maintenance in periodontitis therapy after completion of initial treatment, for gingival pockets up to 5 mm in depth only
• For maintenance in periimplantitis therapy after completion of initial treatment, for gingival pockets up to 5 mm in depth only
Calculi and tartar cannot be removed with Clinpro Prophy Powder.

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)*

K140684: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

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Date:.....March 13, 2014

.....(revised on October 24, 2014)

Name of Device

Proprietary Name:.....Clinpro™ Prophy Powder

Product Code: .....PIP

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

Regulation Number:.....21 CFR 872.6080

Predicate Devices

Air-N-Go® Perio Powder: K110379 by Satelec – Acteon Group, France

Air-Flow® Perio Powder: K092289 by EMS Electro Medical Systems SA, Switzerland

Description for the Premarket Notification

	Clinpro™ Prophy Powder (K021450)	Air-N-Go® Perio Powder (K110379)	Air-Flow® Perio Powder (K092289)	Results of comparison
Powder to be used with air polishing device	Yes	Yes	Yes	Substantially equivalent
Glycine based	Yes	Yes	Yes	Substantially equivalent
Subgingival use	Yes	Yes	Yes	Substantially equivalent
Supragingival use	Yes	Yes	No	Substantially equivalent

Clinpro™ Prophy Powder 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.

As the predicate devices Air-N-Go® Perio Powder (K110379) and Air-Flow® Perio Powder (K092289), Clinpro Prophy Powder is a glycine based air polishing powder to be used with air polishing devices in the professional tooth cleaning.

Comparison of Clinpro Prophy Powder and the predicate devices Air-N-Go® Perio Powder (K110379) and Air-Flow® Perio Powder (K092289) with regard to its indications for use shows that Clinpro Prophy Powder is substantially equivalent to the predicate devices. As the predicate devices, Clinpro Prophy Powder is a powder for sub- and supragingival plaque removal. When applied subgingivally, it may be used as an adjunct to support periodontitis and periimplantitis therapy.

Results of *in vitro* and *in vivo* investigations using Clinpro Prophy Powder and glycine based air-polishing powder (i.a.) published in numerous literature show that Clinpro Prophy Powder is substantially equivalent to the predicate device with regard to the performance of the product.

The particle size of Clinpro Prophy Powder has been determined by laser light diffraction measurement on the particles suspended in isopropanol.

Comparison for indications for use, performance, and chemistry shows that Clinpro Prophy Powder is substantially equivalent to the predicate devices.

Several investigations have been carried out to characterize the performance and safety of Clinpro Prophy Powder and glycine-based powder to be used in professional tooth cleaning. Published *in vitro* and *in vivo* studies support this characterization.

The major focus of the studies evaluated to substantiate performance and safety of Clinpro Prophy Powder was on the following procedures/effects:

- Removal of subgingival bacterial load in supportive periodontal therapy;
- Root debridement;
- Use on contaminated implant material;
- Professional oral hygiene treatment of patients with orthodontic appliances (effects on plaque index (PI) and gingival bleeding);
- Gingival tissue effects;
- Abrasiveness of air-polishing.

The overall conclusion, based also on the clinical literature review, is that Clinpro Prophy Powder is suitable and safe for its intended use.

Biocompatibility testing was carried out. Biocompatibility evaluations have been performed for Clinpro Prophy Powder in consideration of FDA & internationally recognized guidelines. The conclusion of the assessments is that Clinpro Prophy Powder is biocompatible for its intended use.

In summary, it can be concluded that Clinpro Prophy Powder is substantially equivalent in safety and effectiveness with the predicate devices Air-N-Go® Perio Powder (K110379) and Air-Flow® Perio Powder (K092289).

Indications for Use

• Removal of subgingival and supragingival plaque; can also be used in the presence of permanent orthodontic apparatus (brackets) and implants

• For maintenance in periodontitis therapy after completion of initial treatment, for gingival pockets up to 5 mm in depth only

• For maintenance in periimplantitis therapy after completion of initial treatment, for gingival pockets up to 5 mm in depth only

Calculi and tartar cannot be removed with Clinpro Prophy Powder.