February 1, 2022

3M Deutschland GmbH
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220257
Trade/Device Name: Permadyne
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: Class II
Product Code: ELW
Dated: January 28, 2022
Received: January 31, 2022

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K220257

Device Name

Permadyne

Indications for Use *(Describe)*

- Impression of inlay, onlay, crown, bridge, and veneer preparations
- Functional impressions

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Date: ..... November 25, 2021

Trade Name: ..... Permadyne

Common Name: ..... Polyether impression material

Classification Name: ..... Impression material
(21 CFR 872.3660, product code ELW

Device Class: ..... Class II

Predicate Device ..... Permadyne Polyether Rubber Impression (K800031)

Description of Device

The polyether impression material Permadyne consists of the two material components light-bodied consistency and heavy-bodied consistency. It's classified as impression materials (21 CFR 872.3660) because it's intended to reproduce the structure of a patient's teeth and gums. Permadyne is a hand mixed (base paste/catalyst paste) impression material used in one step technique. Thereby Permadyne – Light Bodied Consistency is used as wash material in combination with Permadyne – Heavy Bodied Consistency as tray material. The mixing ratio is 7 volumes base paste :1 volume catalyst paste.

Permadyne – Light Bodied Consistency is a light-bodied polyether impression material. The base paste is blueish colored and the catalyst paste reddish colored.

Permadyne – Heavy Bodied Consistency is a heavy-bodied polyether impression material. The base paste is salmon colored and the catalyst paste reddish colored.

Applicable Standards for Product Tests

- ISO 4823:2015 Dentistry — Dentistry – Elastomeric Impression Materials

Indications for Use for Permadyne reformulated

- Impressions of inlay, onlay, crown, bridge, and veneer preparations
- Functional impressions

Comparison

The reformulated Permadyne was compared to Permadyne (K800031) regarding indications for use, intended use, composition technology and physical and mechanical properties.

The tables below summarize the indications and technology of the reformulated Permadyne and the predicate device:

Permadyne (K800031)	**Permadyne reformulated**
Polyether elastomeric impression material for crowns, bridges and edentulous impression procedures.	• Impression of inlay, onlay, crown, bridge, and veneer preparations • Functional impressions

Table Comparison of indications

Technology	**Permadyne (K800031)**	**Permadyne reformulated**
Heavy-bodied and light-bodied material components	x	x
Material family – Polyether impression material	x	x
Material offered in tubes with base and catalyst pastes	x	x
Manual mixing	x	x

Table Comparison to predicate technology

Permadyne (K800031) and Permadyne reformulated, are both intend to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. Therefore, the intended use of the product is not affected by the change. The indications for use of Permadyne reformulated and the predicate device Permadyne (K800031) are clinically very similar. Permadyne is a precision impression material and therefore suitable for all kinds of impressions. The requirements of an impression material for inlay, onlay, crown, bridge and veneer preparations are comparable as all examples describe the impression of prepared teeth. The impression of an inlay, onlay or veneer don’t require additional or other performance characteristics of the impression material than the impression of a crown or bridge. The procedure “functional impression” describes the impression technique that is used for

edentulous and almost edentulous /partially dentate situations and is therefore don't describe a new condition compared to the edentulous impression procedures description of the predicate. Therefore, 3M Deutschland concludes that Permadyne reformulated is substantially equivalent to the predicate device Permadyne (K800031).

The reformulated Permadyne and Permadyne (K800031) are polyether impression materials containing reactive components, fillers, softeners, setting regulators, flavors, pigments and catalysts. 3M Deutschland GmbH is providing information to the Agency regarding information to FDA about the composition of the reformulated Permadyne and compared this to the predicate device. Considering the results of the biocompatibility evaluation of the reformulated Permadyne material components, it was shown that the new raw material does not have a negative influence on the biocompatibility of the materials. Also, the slightly different quantitative compositions of the reformulated material components in comparison to the predicate's composition submitted to the FDA in 1982 are covered by these favorable biocompatibility evaluations. In addition, the reformulated Permadyne material components fulfil the material performance requirements of ISO 4823:2015. No negative influence of the composition change on the material properties was observed. Therefore, 3M Deutschland GmbH concludes that Permadyne reformulated is substantially equivalent to the predicate device Permadyne (K800031) in technology.

In vitro testing was conducted to show that the reformulated Permadyne fulfils the requirements of FDA recognized standard ISO 4823. Additionally, the reformulated Permadyne was compared to the predicate device Permadyne (K800031) regarding colors, mixing-time, consistency, working time, detail reproduction, linear dimensional change, compatibility with gypsum (type 3 / type 4 or 5), elastic recovery and strain in compression. The results of the reformulated Permadyne fulfill the requirements of ISO 4823 and are similar to Permadyne (K800031). In summary, 3M Deutschland GmbH concludes that the reformulated Permadyne is substantially equivalent to the predicate device regarding performance and physical and mechanical properties.

Biocompatibility

The biocompatibility assessment for the products was conducted in accordance with the following guidance:

Guidance	Edition	Title
US FDA Docket Number FDA-2013-D-0350. CDRH Document Number 1811-R1	September 4, 2020	Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff
ISO 10993-1	20018	Evaluation and testing within a risk management process
ISO 10993-3	2014	Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5	2009	Tests for *in vitro* cytotoxicity
ISO 10993-10	2010	Tests for irritation and skin sensitization
ISO 10993-11	2017	Tests for systemic toxicity
ISO 10993-12	2021	Sample preparation and reference materials
ISO 10993-18	2020	Chemical characterization of materials
ISO/TR 10993-22	2017	Guidance on nanomaterials
ISO 10993-23	2021	Tests for irritation
ISO 7405	2018	Evaluation of biocompatibility of medical devices used in dentistry

The biocompatibility of Permadyne has been assessed by a board-certified toxicologist according to recommendations in FDA guidance and internationally recognized standards for medical and dental devices. The conclusion of the assessment is that Permadyne is safe for its intended use.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device."