May 25, 2021

The Procter & Gamble Company
Michael Kaminski
Principal Scientist
8700 Mason Montgomery Road
Mason, Ohio 45040

Re: K200881
Trade/Device Name: Oral-B *i*O Test Drive Power Brush Trial Program Kit
Regulation Number: 21 CFR 872.6865
Regulation Name: Powered toothbrush
Regulatory Class: Class I
Product Code: JEQ

Dear Michael Kaminski:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 27, 2020. Specifically, FDA is updating this SE Letter for typographical errors in the company name and regulatory class as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6276, Michael.Adjodha@fda.hhs.gov.

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

August 27,2020

The Proctor & Gamble Company
Michael Kaminski
Principal Scientist
8700 Mason Montgomery Road
Mason, Ohio 45040

Re: K200881
Trade/Device Name: Oral-B iO Test Drive Power Brush Trial Program Kit
Regulation Number: 21 CFR 872.6865
Regulation Name: Powered Toothbrush
Regulatory Class: Class I, reserved
Product Code: JEQ
Dated: August 5, 2020
Received: August 6, 2020

Dear Michael Kaminski:

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,

Bobak Shirmohammadi -S

for Srinivas "Nandu" Nandkumar, Ph. D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): To Be Assigned

Device Name: Oral-B® *i*O Test Drive Power Brush Trial Program Kit

Indications for Use:

The Oral-B® *i*O Test Drive Power Brush Trial Program Kit is intended for use as a power toothbrush to promote good oral hygiene.

The Oral-B® *i*O Test Drive Power Brush Trial Program Kit is indicated for use under the direct supervision of a dental professional, exclusively at conventions (e.g. professional, scientific, trade shows), as part of the Oral-B® *i*O Test Drive Power Brush Trial Program.

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)

Procter&Gamble

The Procter & Gamble Company
Mason Business Center
Mason, Ohio 45040-9462

5. 510(k) Summary

K200881

SUBMITTER

510(k) Owner: The Procter & Gamble Company
1 Procter & Gamble Plaza Cincinnati, Ohio 5202
Telephone: (513) 206-4331
Establishment Registration Number: 9915005

Contact Person: Michael A. Kaminski Ph.D.
Principal Scientist Oral Care
The Procter & Gamble Company
Telephone: (513) 206-4331 Email: kaminski.ma@pg.com

Date Prepared: August 26, 2020

DEVICE

Trade Name: Oral-B® *i*O Test Drive Power Brush Trial Program Kit

Common Name: Power Toothbrush

Classification Name: Toothbrush, Powered

Product Code: JEQ

PREDICATE / REFFERENCE DEVICE

The Oral-B® *i*O Test Drive Power Brush Trial Program Kit ("program kit") is substantially equivalent to the predicate Oral-B® Test Drive Power Brush Trial Program Kit marketed by Procter & Gamble, Premarket Notification Number: K141018, FDA Product Code JEQ (Class I, 510(k) Exempt).

The Oral-B® *i*O Test Drive Power Brush Trial Program Kit uses as a reference device the Oral-B® *i*O Rechargeable Toothbrush; a class I, 510(k) exempt device. The reference device is available as an over-the-counter device marketed under regulatory reference number 21 CFR 872.6865. The Oral-B® *i*O Rechargeable Toothbrush is cited as a reference device because it is for all intents and purposes, the same device as the subject device. The reference device, a 510k exempt device, is compliant with ISO 20127, *Dentistry - Powered toothbrushes - General requirements and test methods* which we also relied on to demonstrate the performance of the subject device. Additionally, with the exception of the colorant in the adapter which was used in the predicate, all the materials found in the reference device are used in the subject device.

Neither the predicate device nor the reference device have been the subject of any design-related recalls.

DEVICE DESCRIPTION

The Oral-B® iO Test Drive Power Brush Trial Program for conventions (e.g. professional, scientific, trade shows), is designed to introduce convention delegates to the newest, most advanced Oral-B electric rechargeable toothbrush as a means to promote good oral hygiene. The program kit contains a power toothbrush consisting of a rechargeable handle, a charger, replacement brush heads, and instructions for the proper use and care of the device. The program kit also contains plastic dental sheaths to prevent soiling and therefore allowing for easier cleaning of the multi-user handle. The sheath is manufactured by TIDI Products, LLC, is provided to Procter & Gamble as a finished, packaged non-sterile device (K132953) for inclusion in the program kit as an accessory. Detailed instructions for cleaning and disinfection of the reusable handle are also included. The program kit is indicated for use as an introductory trial, exclusively within the confines of a convention (e.g. professional, scientific, trade shows), under the direct supervision of a dental professional as part of the Oral-B® iO Test Drive Power Brush Trial Program.

INDICATIONS FOR USE

The Oral-B® iO Test Drive Power Brush Trial Program Kit is intended for use as a power toothbrush to promote good oral hygiene.

The Oral-B® iO Test Drive Power Brush Trial Program Kit is indicated for use under the direct supervision of a dental professional, exclusively at conventions (e.g. professional, scientific, trade shows), as part of the Oral-B® iO Test Drive Power Brush Trial Program.

The indication for use for the subject device differs from that of the predicate in that we have narrowed the use environment to conventions only. The results in user group, those who will brush their teeth, being a sub population of the predicates target population. The more controlled use environment also allows for the assurance of a regimented and standardized training program to insure proper cleaning and disinfection of the device after use. These differences in indication for use do not affect the safety and effectiveness of the device when used as labeled.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Oral-B® iO Test Drive Power Brush Trial Program Kit is substantially equivalent to the predicate device, Oral-B® Test Drive Power Brush Trial Program Kit (K141018). The Oral-B® iO Test Drive Power Brush Program Kit that is the subject of this 510(k) differs slightly from the predicate with regards to design, dimensions and materials yet none of these modifications affect the safety or effectiveness of the device. The most notable difference between the Oral-B® iO Test Drive Power Brush Trial Program Kit and the predicate device are a new drive mechanism and elimination of the elastomeric seal that previously presented a physical barrier to saliva and other fluids from potentially contaminating the handle drive shaft. These changes necessitated a change to the reprocessing, including the use of an FDA-cleared high-level disinfectant and is the reason for this pre-market notification. In addition, the target population for the subject device is much more specific in that the Oral-B® iO Test Drive Power Brush Trial Program will be executed at conventions only under the direct supervision of a dental professional and the device cleaned and disinfected by trained professionals. The subject device, the reference and predicate are all manufactured by Procter & Gamble Manufacturing GmbH (Marktheidenfeld, Germany) and distributed in the U.S.A. by Procter & Gamble, Co. (Cincinnati, Ohio).

The OTC Oral-B® iO Rechargeable Power Toothbrush (reference device) for all intents and purposes, is the same device as the subject device. Marketed as class I, 510k exempt device, the reference device is available for purchase OTC for consumers and satisfies all the requirements of a class I 510k exempt device including compliance with ISO 20127, Dentistry - Powered toothbrushes - General requirements and test methods.

While there are differences in indication for use, use environment, color of the adapter, software and labelling all have been addressed in the 510k with data that supports a finding of substantial equivalence to the predicate.

Summary of Technological Characteristics

	Subject Device	Predicate Device	Reference Device
510(k) Number	To be assigned	K141018	Class I, 510(k) exempt
Product Code	JEQ	JEQ	JEQ
Common Name	Toothbrush, Powered	Toothbrush, Powered	Toothbrush, Powered
Trade Name	Oral-B® *i*O Test Drive Power Brush Trial Program Kit	Oral-B® Test Drive Power Brush Trial Program Kit	Oral-B® *i*O Rechargeable Power Toothbrush
FDA Class	Class I, 510(k) exempt, Rx	Class I, 510(k) exempt, Rx	Class I, 510(k) exempt, OTC
Regulation	21CFR§872.6865	21CFR§872.6865	21CFR§872.6865
Manufacturer	Procter & Gamble Manufacturing GmbH	Procter & Gamble Manufacturing GmbH	Procter & Gamble Manufacturing GmbH
Sold Sterile	No	No	No
Description	The Oral-B® *i*O Test Drive Program allows users to experience the benefit of brushing with an electric rechargeable toothbrush specifically within a convention setting	The Oral-B® Test Drive Power Brush Trial Program Kit is a rechargeable power toothbrush designed to promote good oral hygiene, including the reduction of dental plaque for the treatment and prevention of gingivitis.	The Oral-B® *i*O Power Toothbrush is a rechargeable power toothbrush designed to promote good oral hygiene, including the reduction of dental plaque for the treatment and prevention of gingivitis.
Indication for Use	The Oral-B® *i*O Test Drive Power Brush Trial Program Kit is intended for use as a power toothbrush to promote good oral hygiene. The Oral-B® *i*O Test Drive Power Brush Trial Program Kit is indicated for use under the direct supervision of a dental professional, exclusively at conventions (e.g. professional, scientific, trade shows), as part of the Oral-B® *i*O Test Drive Power Brush Trial Program.	The Oral-B® Test Drive Power Brush Trial Program Kit is intended for use as a power toothbrush to promote good oral hygiene, including the reduction of dental plaque, for the treatment and prevention of gingivitis. The Oral-B® Test Drive Power Brush Trial Program Kit is indicated for use under the supervision of a dental professional as part of the Oral-B® Test Drive Power Brush Trial Program.	The Oral-B® *i*O Power Toothbrush is intended for use as a power toothbrush to promote good oral hygiene by removing adherent plaque and food debris from the teeth to reduce tooth decay and treat and prevent gingivitis.
Use Environment	Convention (e.g. professional, scientific, trade show) under the direct supervision of a dental professional.	Dental Office under the supervision of a dental professional.	Home

	Subject Device	Predicate Device	Reference Device
Target Population	Convention attendee (e.g. dentist, hygienist, dental researcher) under the direct supervision of a dental professional (18 years or older). Dental professionals (e.g. dentist, hygienist, assistants, students) responsible for the cleaning and disinfection of the handle will be trained and supervised (18 years or older).	Consumer use under dental professional supervision (General population 3 years and above). Dental professionals (e.g. dentist, hygienist, assistants) responsible for the cleaning and disinfection of the handle did not receive any training or supervision (18 years or older).	Over-the-Counter – General population (3 years and above)
Components	Oral-B® *i*O Test Drive Power Brush Trial Program Kit (2 boxes): • Oral-B® *i*O Test Drive Power Toothbrush Kit (1 box) ○ Handle (1) ○ Charger (1) ○ User Manual (1) • Oral-B® *i*O Test Drive Refill Kit (1 box) ○ Oral-B® *i*O brush heads (25) ○ Plastic Sheaths (30) ○ Cleaning and Disinfection Quick Reference Guide (1) Cleaning and Disinfection Manual (1)	Oral-B® Test Drive Power Brush Trial Program Kit (2 boxes): • Oral-B® Test Drive Power Toothbrush Kit (1 box) ○ Handle (1) ○ Charger (1) ○ User Manual (1) • Oral-B® Test Drive Refill Kit (1 box) ○ Oral-B® brush heads (50) ○ Plastic Sheaths (55) Cleaning and Disinfection Manual (1)	Oral-B® *i*O Power Brush (1 box): ○ Handle (1) ○ Charger (1) ○ Oral-B® brush heads (vaiable) ○ User Manual (1)
Model	Program Kit – Product code 80338870 Handle – OPO24 Brush Head – ORO20 Charger – OPO23	Program Kit – D34.503.5e Handle – D34e Brush Head – EB50e Charger – 3757	OTC Kit - Product code 80338571 Handle – OPO20 Brush Head – ORO15 Charger – OPO23
Accessory	Disposable plastic sheath to prevent soiling and facilitate cleaning (K132953)	Disposable plastic sheath to prevent soiling and facilitate cleaning (K132953)	No Applicable
Labeling	○ User Manual ○ Cleaning and Disinfection Manual with Quick Start Guide ○ Training Script ○ Checklist for Validation and Revalidation	○ User Manual ○ Cleaning and Disinfection Manual	○ User Manual

	Subject Device	Predicate Device	Reference Device
Cleaner	Opti-Cide^3 Solution (EPA Reg. No. 70144-1) Micro-Scientific, LLC Ingredients: 0.154% n Alkyl (60% C_{14} 30% C_{15} 5% C_{12} 5% C_{18}) dimethyl benzyl ammonium chloride, 0.154% n Alkyl (68% C_{12} 32% C_{14}) dimethyl benzyl ammonium chloride, 21% Isopropanol Contact Conditions: 2 min at 20ºC Or **General Purpose Non-Ammoniated Ultrasonic Cleaner** (e.g. Crosstex) Crosstex international Ingredients: <5% Isopropyl alcohol, <5% Soda Ash, <5% Ethoxylated Alcohols Phosphate esters (C8-10) Contact Conditions: 2 min at 20ºC	Opti-Cide^3 Surface Wipes (EPA Reg. No. 70144-1) Micro-Scientific, LLC Ingredients: 0.154% n Alkyl (60% C_{14} 30% C_{15} 5% C_{12} 5% C_{18}) dimethyl benzyl ammonium chloride, 0.154% n Alkyl (68% C_{12} 32% C_{14}) dimethyl benzyl ammonium chloride, 21% Isopropanol Contact Conditions: 30 seconds at 20ºC	Not applicable

	Subject Device	Predicate Device	Reference Device
Disinfection	Spaulding classification – Semi-critical High Level Disinfection **Resert XL HLD High Level Disinfectant** (K091022/K080420) Steris Corporation Active: 2.0% hydrogen peroxide Contact Conditions: 8 min at 20ºC 21 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.	Spaulding classification – Non-critical Intermediate Level Disinfection **Opti-Cide 3 Solution** (EPA Reg. No. 70144-1) Micro-Scientific, LLC Active: 0.154% n Alkyl (60% C_{14} 30% C_{15} 5% C_{12} 5% C_{18}) dimethyl benzyl ammonium chloride, 0.154% n Alkyl (68% C_{12} 32% C_{14}) dimethyl benzyl ammonium chloride, 21% Isopropanol Contact Conditions: 3 min at 20ºC	Not intended to be disinfected
Reuse Life	100 cycles	240 cycles	5 years
Biocompatibility	Yes – materials plus experience on similar devices plus post-marketing data on similar devices; materials are same as those used in the predicate and reference device. Risk Assessment ISO 10993-1 Cytotoxicity ISO 10993-5 Irritation ISO 10993-12 Sensitization ISO 10993-10	Yes – materials plus experience on similar devices plus post-marketing data on this device and similar devices; materials are same as those used in the marketed predicate.	Yes – materials plus experience on similar devices plus post-marketing data on this device and similar devices; materials are same as those used in the marketed device.
Software	Yes – consistent with the Level of Concern – Moderate	Yes – consistent with the Level of Concern – Minor	Yes – consistent with the Level of Concern – Minor
Electrical Safety and Electromagnetic Compatibility	UL 1431 IEC 60355-1 IEC 60335-2-52 } ISO 20127 Title 47 CFR Parts 15B, 15C and 18	UL 1431 IEC 60355-1 IEC 60335-2-52 } ISO 20127 Title 47 CFR Parts 15B, 15C and 18	UL 1431 IEC 60355-1 IEC 60335-2-52 } ISO 20127 Title 47 CFR Parts 15B, 15C and 18

PERFORMANCE DATA

Biocompatibility Testing
Biocompatibility was demonstrated through testing that was consistent with ISO 10993 and FDAs guidance on how to use ISO 10993-1 within a risk management process. The subject device is intended to come in limited direct contact with intact skin and limited indirect contact with oral mucous membranes. The results from cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-12) studies passed all tests in conformity with the standards and moreover the testing confirmed that after cleaning and disinfection the subject device was non-cytotoxic, non-sensitizing, and non-irritating.

Electrical Safety and Electromagnetic Compatibility
Electrical safety testing in accordance with UL 1431, IEC 60335-1 and IEC 60335-2-52 (as outlined in ISO 20127) was applied with compliant results. This testing confirms that the construction of the system addresses risk of fire, shock and physical injury to the degree specified by these consensus standards.

Electromagnetic compatibility testing was performed with compliant results in accordance with the Title 47 CFR Parts 15B, 15C and 18 of the Federal Communications Commission. This testing assures that the unintentional and intentional radiation are within the federally proscribed limits across the full RF bandwidth.

Software Verification and Validation Testing
Software verification and validation was completed in accordance with the FDA guidance documents, "General Principles of Software Validation" (issued January 11, 2002). Supporting documentation, consistent with the software's Level of Concern statement, has been submitted in accordance with the FDA guidance document "Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005). The results from the verification and validation activities demonstrate that the device performs as intended.

Cleaning and Disinfection Validation Testing
Cleaning and disinfection validation testing for the program kit was performed under conditions that simulated normal use and worst-case scenario for wear. The testing demonstrated that the cleaning and disinfection procedures result in satisfactory cleaning and high-level disinfection of the device, and that the repeated exposure of the handle to cleaning and disinfection procedures had no effect on the physical characteristics or performance of the device. Repeated exposure of the device to simulated use conditions including cleaning and disinfection established the reuse life of 240 uses and subsequent cleaning and disinfection cycles.

Human Factors Usability testing

Several formative and a summative Human Factors Usability studies were performed to evaluate the ability of the users of the device to read and comply with the instructions for use for the assembly, operation, and care of the Oral-B® *i*O Test Drive Power Toothbrush. The formative studies were designed and conducted to help develop and test the use instructions, software and training necessary to insure proper cleaning and disinfection of the reusable handle. The

summative study was designed and performed to validate that the users of the *i*O Oral-B® Test Drive Power Brush Trial Program could after training, read and understand the product labeling and follow the instructions with the aid of the software to properly clean and disinfect the reusable toothbrush handle.

CONCLUSION

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K141018).