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

May 20, 2016

Young Dental Manufacturing Co 1, LLC.
Ms. Sarah Moore
Director of Quality and Regulatory Affairs
13705 Shoreline Ct. East
Earth City, Missouri 63045

Re: K153334
Trade/Device Name: Oral-B 5% Sodium Fluoride Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: April 14, 2016
Received: April 18, 2016

Dear Ms. Moore:

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" (21 CFR 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,

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 below.

510(k) Number *(if known)*
K153334

Device Name
Oral-B 5% Sodium Fluoride Varnish

Indications for Use *(Describe)*
Oral-B 5% Sodium Fluoride Varnish is a fluoride-containing preparation for the treatment of dentinal hypersensitivity and for the reduction of post-operative sensitivity.

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.

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510(k) Summary
K153334

Sponsor:	Young Dental Manufacturing Co. 1 LLC 13705 Shoreline Ct. East Earth City, MO 63045
Contact Person:	Sarah Moore Quality/Regulatory Affairs Telephone: 314-372-8040 Fax: 314-344-0021
Date:	May 06, 2016
Trade Name:	Oral-B 5% Sodium Fluoride Varnish
Common Name:	Cavity Varnish
Classification Names and References:	Varnish, Cavity 21 CFR 872.3260, LBH
Classification Panel:	Dental
Predicate Device(s):	VarnishAmerica 5% Sodium Fluoride Varnish, Medical Products Laboratories, Inc. K040098, cleared February 4, 2004
Purpose and Description	Oral-B 5% Sodium Fluoride Varnish is a fluoride-containing preparation for the treatment of dentinal hypersensitivity, and for the reduction of post-operative sensitivity. 1mL of varnish contains 50 mg of sodium fluoride, equivalent to 22.6 mg fluoride ion. Varnish is sweetened with sucralose and Xylitol, and flavored. Varnish and applicator are packaged together in a molded opaque acclar tray, and sealed with a metallized foil.
Intended Use:	Oral-B varnish is a fluoride-containing preparation for the treatment of dental hypersensitivity, and for the reduction of post-operative sensitivity.
Technological Characteristics	The fundamental principle and primary mode of action of both the Oral-B varnish and the predicate in reducing

dental hypersensitivity is the occlusion of open dentin tubules. Oral-b and the predicate exist as a viscous liquid that is able to be applied to the teeth using a brush or similar applicator. Both the Oral-B and the predicate employ 5% sodium fluoride as the source of fluoride ions for the formation of calcium fluoride which occludes the dentin tubules. Both use denatured alcohol as a significant component, providing fluidity for application and to promote quick drying on the tooth surface.

The technological difference between the Oral-B varnish and the predicate is the formulation of components. The Oral-B varnish uses a synthetic resin as the base material instead of the natural rosin used in the predicate. Oral-B also includes an additional base material, sweeteners, and flavoring agents.

Comparison to Predicate Device: The table below summarizes the similarities and differences between Oral-B 5% Sodium Fluoride Varnish and the predicate device:

	Oral-B 5% Sodium Fluoride Varnish	**VarnishAmerica 5% Sodium Fluoride Varnish- Predicate Device**
	K153334	**K040098**
Indications for use	Treatment of dental hypersensitivity and Reduction of post-operative sensitivity	Treatment of dental hypersensitivity and Reduction of post-operative sensitivity
Contraindications	Ulcerative gingivitis and stomatitis	Ulcerative gingivitis and stomatitis
Mode of action	Dentin Tubule Occlusion	Dentin Tubule Occlusion
Method of application	Application of a thin coat of varnish on tooth surfaces	Application of a thin coat of varnish on tooth surfaces
Percentage of sodium fluoride	5%	5%
Packaging	Varnish and applicator brush placed in a molded opaque acclar tray and closed with a foil seal	Varnish and applicator brush placed in a molded opaque acclar tray and closed with a foil seal
Unit package	0.4mL	0.4mL
Base Material	Synthetic Rosin	Natural Rosin

Performance Data (Nonclinical):

Fluoride Release and Dentin Tubule Occlusion Performance – Comparative bench testing with the predicate was carried out by independent laboratories. Bench testing confirmed that the fluoride release and tubule occlusion characteristics of Oral-B varnish are as expected and comparable to the predicate.

- **Shelf Life –** The shelf life of this device is declared to be 24 months in accordance with defined protocols and acceptance specifications and have provided the rationale for establishment of this shelf life.

- **Biocompatibility** – Oral-B varnish and the predicate were tested for cytotoxicity per ISO 10993-5 with equivalent results. Oral-B varnish was also tested for irritation and sensitization per ISO 10993-10. Test results provide evidence of biocompatibility.

Performance Data (Clinical):

Clinical data were not needed for these devices to show substantial equivalence.

Conclusions:

The information presented in this submission including composition and indications for use, together with biocompatibility and non-clinical performance testing establish that Oral-B varnish is substantially equivalent to the predicate.