November 6, 2020

Dr. Collins, Inc.
Jiahe Li
Regulatory Affair Associate
4330 Barranca Pkwy. Ste #100
Irvine, California 92604

Re: K200077
Trade/Device Name: BioMin Restore Plus
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: July 19, 2020
Received: August 10, 2020

Dear Jiahe Li:

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,

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

Section IV

Indications for Use Statement

510(k) Number (if known): K200077

Device Name: BioMin® Restore Plus

Indications for Use:

Prescription fluoride dentifrice for use in the prevention and treatment of dental sensitivity.

Prescription Use ___X___ OR Over-The-Counter Use_____

Section V

510(k) Summary

Submitter:
Dr. Collins, Inc.
4330 Barranca Pkwy. Ste #100
Irvine, CA 92604
Contact Person:
Jiahe Li
Regulatory Affairs Manager
Lijh0919@gmail.com

Date Summary Prepared:
November 4th, 2020

DEVICE NAME

TRADE NAME: BioMin® Restore Plus

COMMON NAME: Dentifrice, Toothpaste

DEVICE CLASS: Class II

CLASSIFICATION NAME: Cavity Varnish

CLASSIFICATION PRODUCT CODE: LBH

510(K) NUMBER: K200077

REGULATION NUMBER: 21 CFR 872.3260.

PREDICATE DEVICE

Primary Predicate Decice: Restore Toothpaste - Dr. Collins, Inc. - K181965

Reference Device: Voco Paste - VOCO GMBH - K101104

DESCRIPTION OF DEVICE

BioMin® Restore Plus is a daily-use, prescription fluoride dentifrice use in the prevention and treatment of dental sensitivity through physical occlusion of dentin tubules. The formulation incorporates BioMin™ F (Calcium Fluoro-Phosphosilicate, a particular form of bioactive glass) as its active ingredient. When exposed to an aqueous environment, BioMin™ F undergoes a rapid surface reaction to form Fluorapatite, which is chemically and structurally similar to natural tooth mineral, allowing it to physically occlude tubules.

INDICATIONS FOR USE

Prescription fluoride dentifrice for use in the prevention and treatment of dental sensitivity.

Technological Characteristics

The fundamental principle and mode of action of BioMin® Restore Plus is the same as the predicate devices. All three devices are designed to reduce dentinal hypersensitivity through the physical occlusion of open dentin tubules by the formation of an apatite layer.

BioMin™ F (Calcium Fluoro-Phosphosilicate, a particular form of bioactive glass) is the active ingredient in BioMin® Restore Plus's formulation. When exposed to an aqueous environment, BioMin™ F undergoes a rapid surface reaction to form Fluorapatite, which is chemically and structurally similar to natural tooth mineral, allowing it to physically occlude tubules.

Performance Tests

The formula of BioMin® Restore Plus was tested for its ability to reduce dentine hypersensitivity through physical occlusion of dentine tubule and its relative abrasion level of dentine and enamel.

The dentine tubule occlusion test result indicates that BioMin® Restore Plus is as effective as the primary predicate device at dentine tubule occlusion. Meanwhile, the Relative Dentin Abrasivity (RDA) value is similar to the primary predicate and is well under the limit considered safe for daily use (<250) established by American Dental Association (ADA).

Biocompatibility

Different biocompatibility tests in accordance with ISO10993 have been performed on the subject

device. Meanwhile, a biological evaluation and a toxicological risk assessment have also been conducted on the subject device. The results of these tests and studies indicate there is no evidence of any hazardous effects and the subject device is safe for its intended use.

Device Comparison Table

Element of Comparison	**Subject Device** BioMin® Restore Plus	**Primary Predicate Device** Restore Toothpaste – K181965	**Reference Device** Voco Paste – K101104	**Substantially Equivalent**	**Remarks**
Intended Use	For dental hypersensitivity relief	For dental hypersensitivity relief	For dental hypersensitivity relief	Yes	--
Indications for Use	Prescription fluoride dentifrice for use in the prevention and treatment of dental sensitivity.	A daily use over-the-counter toothpaste formulated to provide rapid and continual tooth sensitivity relief.	Intended to be used after professional tooth whitening, professional tooth cleaning and for prevention and control of hypersensitivities.	Yes	The only difference is that the subject device and reference device are for prescription use, while the primary predicate device is for OTC use.
Design	Paste/gel that is applied to the tooth using an applicator brush or similar application.	Paste/gel that is applied to the tooth using an applicator brush or similar application.	Paste/gel that is applied to the tooth using an applicator brush or similar application.	Yes	--
Composition of Material	Apatite forming ingredient, filler, surfactant, thickening agent, colorant,	Apatite forming ingredient, filler, surfactant, thickening agent, colorant,	Apatite forming ingredient & hydroxyapatite, filler, surfactant, thickening agent, colorant, sweetener & flavor enhancer.	Yes	The subject device and the primary predicate device have exact the same composing ingredients, except for the active ingredients, which are also

		sweetener & flavor enhancer.	sweetener & flavor enhancer.			compositionally and structurally very similar.
Technological Characteristics	**Mode of Action**	Physical occlusion of dentin tubules	Physical occlusion of dentin tubules	Physical occlusion of dentin tubules	Yes	--
	Principle of Action	Occlude dentin tubules through reaction with saliva and subsequent formation of apatite layer	Occlude dentin tubules through reaction with saliva and subsequent formation of apatite layer	Occlude dentin tubules through reaction with saliva and subsequent formation of apatite layer and direct occlusion with pre-formed hydroxyapatite particles	Yes	The technological characteristics between the subject device and primary predicate are the same. The reference device differs slightly in that it also contains some pre-formed hydroxyapatite particles which can occlude dentine tubule directly.
Biocompatibility		Yes	Yes	Yes	Yes	--

Conclusion

Based on the comparison of the compositions and actions, as well as the testing data provided, BioMin® Restore Plus is considered to be substantially equivalent to the identified legally marketed predicate devices.