



Food and Drug Administration
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Silver Spring, MD 20993-0002

January 29, 2015

Johnson & Johnson Healthcare Products
Division of McNeil-PPC, Inc.
C/O Ms. Angelina M. Hunt, RAC
Director, Regulatory Affairs
199 Grandview Road
Skillman, New Jersey 08558

Re: K143155

Trade/Device Name: Listerine[®] Sensitivity Defense[™] Mouthwash
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: II
Product Code: LBH
Dated: October 31, 2014
Received: November 3, 2014

Dear Ms. Hunt:

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,

 Tina
Kiang -S

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

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number, if known: K143155

Device Name: Listerine[®] Sensitivity Defense Mouthrinse

Indications for Use:

Provides continual relief from tooth sensitivity due to cold, heat, acids, sweets, or contact.
Over-the-counter use.

Prescription Use _____ OR Over-the-Counter Use X _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5 - 510(k) SUMMARY

I. Submitter Information

Name: Johnson & Johnson Healthcare Products
Division of McNeil-PPC, Inc.
Address: 199 Grandview Rd.
Skillman, NJ 08558

Contact: Angelina M. Hunt, RAC
Phone: (908) 874-2943
Facsimile: (908) 904-3712
Email: ahunt2@its.jnj.com

Date Prepared: October 30, 2014

II. DEVICE

Name of Device: Listerine® Sensitivity Defense™ Mouthrinse
Common or Usual Name: Mouthwash / Oral Rinse
510(k) Number: K143155
Regulatory Class: II
Classification Name: Cavity Varnish (21 CFR 872.3260)
Product Code: LBH

III. PREDICATE DEVICE

Predicate Device: Colgate® Desensitizing Mouthwash
510(k) Number: K140481
Applicant: Colgate-Palmolive Company

Predicate Device: Oralief™ OTC Toothpaste for Sensitive Teeth
510(k) Number: K080228
Applicant: NovaMin Technology, Inc.

To our knowledge, the predicate devices have not been subject to a design-related recall.

The following reference device is listed below.

Reference Device: Crest® Sensi-Stop Sensitivity Relief Strips (Sylphar
Remesense)
510(k) Number: K132426

Applicant: Sylphar N.V.

To our knowledge, the reference device has not been subject to a design-related recall.

IV. Device Description

Listerine® Sensitivity Defense™ Mouthrinse (LSDM) is a formulated device containing Dipotassium oxalate directed for twice-daily use to provide continual dentinal sensitivity relief. The oxalate formula relieves this painful tooth sensitivity by physically occluding dentinal tubules, preventing hydrodynamic flow, thereby preventing the painful stimulation of nerves within the tooth.

V. INDICATIONS FOR USE

Intended Use: Relieves tooth sensitivity.

Indications for Use: Provides continual relief from tooth sensitivity due to cold, heat, acids, sweets or contact. For over-the-counter use.

The Indications for Use statement for the LSDM is the same as the listed predicate devices. They are generally all indicated for providing relief from tooth sensitivity due to cold, heat, acids, sweets or contact. Additionally, the subject device and predicate devices are available over-the-counter for home use and have the same intended use for the relief of tooth sensitivity.

VI. COMPARISON OF TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use, oral application and fundamental technology of the Listerine Sensitivity Defense Mouthrinse device is substantially equivalent to the predicate devices, Colgate Desensitizing Mouthwash and Oralief toothpaste for Sensitive Teeth. These devices contain a formulated occlusion technology that blocks the hydrodynamic flow within the open tubules. Open dentin tubules allow the fluid to transmit external stimuli to the nerves within the dentin pulp and to trigger a pain response, resulting in dentinal hypersensitivity. The components in the LSDM device physically form a thin film that acts like a seal, thereby physically restricting fluid movement through the dentin tubules and preventing external stimuli from triggering the pain response. The physical mechanism of action is responsible for the product's ability to achieve its intended purpose.

Technological characteristics differ in each formula composition between the subject device and the predicates; however, the fundamental scientific technology responsible for how the device achieves its intended use is the same.

Table1: Intended Use and Technical Characteristic Comparison

Device	Classification Name	Intended Use	Technical Composition/ Occluding Component	Fundamental Technology / Mechanism of Action	Usage Form
Listerine® Sensitivity Defense™ Mouthrinse (LSDM) (K143155)	Cavity Varnish	Relief from tooth sensitivity	Dipotassium Oxalate	Occlusion of dentinal tubules	Mouthwash/ Oral rinse
Predicate Colgate® Desensitizing Mouthwash (K140481)	Cavity Varnish	Relief from tooth sensitivity	Arginine	Occlusion of dentinal tubules	Mouthwash/ Oral rinse
Predicate Oralief™ OTC Toothpaste for Sensitive Teeth (K080228)	Cavity Varnish	Relief from tooth sensitivity	Calcium sodium phosphosilicate (Novamin Technology)	Occlusion of dentinal tubules	Non-aqueous Toothpaste
Reference Device Crest® Sensi-Stop Sensitivity Relief Strips (Sylphar Remesense) (K132426)	Cavity Varnish	Relief from tooth sensitivity	Oxalic Acid, Potassium Salt	Occlusion of dentinal tubules	Gel strips

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the LSDM device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standards (ISO) ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,” and ISO-7405:2008 – Dentistry – Preclinical evaluation and biocompatibility of medical devices used in dentistry, as recognized by the FDA.

Biocompatibility results indicate that all components in the LSDM device comply with the ISO standards:

- ISO-10993-10:2010 – Maximization Test for Delayed-Type Hypersensitivity
- ISO-10993-10:2010 – Oral Mucosa Irritation Test
- ISO-10993-5:2009 - Cytotoxicity

Bench Performance Testing

The LSDM device was tested in *in-vitro*, using recognized methods for dentin occlusion including scanning electron micrographs. Hydraulic conductance testing of the subject device using Dentin Permeability model demonstrated physical occlusion of dentin tubules compared to similar device controls based on various occlusion technologies.

Clinical Performance Testing

A multi-center, double-blind, randomized, parallel-group study, controlled clinical study was conducted to determine the safety and effectiveness for the LSDM device in reducing and controlling dentinal hypersensitivity.

375 subjects were evaluated with 186 in the placebo group and 189 in the test product group. The subjects had at least two teeth that satisfied the qualifying response to stimuli for sensitivity measures (air blast and tactile). Evaluations occurred at baseline, 2 and 4 weeks. Results indicated that the test product group provided a statistically significant improvement relative to the placebo group for all primary and secondary measures at 2 and 4 weeks. In summary, in this study, the LSDM device was demonstrated to be superior to the placebo group in both the primary and the key secondary efficacy endpoints.

During the study, 7 of the subjects in the test group and 8 in the placebo control group experienced self-limiting adverse events which all resolved. All of the adverse events considered related to the test product group were mild to moderate and resolved without treatment or a change in study product usage. These were not unexpected adverse events for an oral rinse product. There were no serious adverse events during the study.

The results of the study conclude that the LSDM device showed statistically significant reductions in hypersensitivity at 2 and 4 weeks with twice-daily use supporting device effectiveness. All mild to moderate adverse events in the study groups resolved without treatment or change in study product usage and no serious adverse events were observed.

Summary

This study demonstrated that the LSDM device used twice daily as an adjunct to toothbrushing provided significantly greater efficacy in reducing and controlling dentinal hypersensitivity compared to a placebo mouth rinse. There were no serious adverse events during the study and the LSDM device was well tolerated. The LSDM device has been tested in non-clinical and clinical testing and has been shown to be safe and effective for its intended use.

VII. Conclusion

Based on the results of non-clinical and clinical testing on the LSDM device, the mouthrinse device is at least as safe and effective as the predicate devices through toxicological safety assessments, stability and in-vitro and clinical performance testing, therefore supporting that the LSDM device meets its intended use and is substantially equivalent to the predicate devices.