510(k) Number K091964
Summary

SEP 2 4 2009

Applicant:	Procter & Gamble 8700 Mason-Montgomery Road Mason, OH 45202
Applicant Correspondent:	Victoria P. Schofield, Pharm.D. Regulatory Affairs Manager Procter & Gamble 8700 Mason-Montgomery Road Mason, OH 45040 Telephone: (513) 622-4851 Fax: (513) 622-1907 E-mail: schofield.vp@pg.com
Date Summary Prepared:	September 04, 2009
Proprietary Name of Device:	Crest Glide Dental Floss
Generic/Classification Name:	Dental floss
Product Code (Classification):	JES (Class I, 21CFR 872.6390)
Legally Marketed Predicate Devices:	Glide Comfort Plus Dental Floss Oral-B Toothbrush (K073224)

Device Description and Technical Characteristics: Crest Glide dental floss is a manual dental floss comprised of polytetrafluoroethylene monofilament fiber and a coating comprised of beeswax, gum arabic, water, flavor and other ingredients for color and cosmetic benefits. The floss was developed to improve ease of sliding between tight spaces to achieve effective plaque removal. Each of the materials that could come in contact with the user of this device is comprised of well-defined materials that are safe for use in the oral cavity.

Indication for Use: To remove plaque and food particles from between the teeth as part of a comprehensive dental treatment program to reduce tooth decay and to treat and prevent gingivitis.

Supporting Information: Two substantially equivalent predicates have been provided, as well as clinical data to support the expanded indication.

- Currently marketed Glide Comfort Plus Dental Floss has the same design and manufacturing process as the Crest Glide Dental Floss and is indicated for removal of plaque and prevention of tooth decay. Crest Glide Dental Floss uses the same mechanism of action (mechanical removal of plaque) to provide treatment and prevention of gingivitis. There are no new issues of safety or effectiveness.
- Currently marketed Oral-B Toothbrush is indicated for treating and preventing gingivitis and uses the same mechanism of action as Crest Glide Dental Floss (mechanical removal of plaque) to achieve this benefit. There are no new issues of safety or effectiveness.
- Data from four clinical trials are provided that collectively show the addition of dental floss to tooth brushing is effective at treatment and prevention of gingivitis via the

physical removal of plaque. The floss treatments in these studies were well tolerated with no safety issues.

Conclusions: Crest Glide Dental Floss is substantially equivalent to Glide Comfort Plus Dental Floss and Oral-B Toothbrush without raising any new safety and effectiveness issues. In addition, clinical data support the indication of treatment and prevention of gingivitis for dental floss above that provided by tooth brushing alone.

Bibliography

1. **Assessment of treatment responses to dental flossing in twins.** Biesbrock A, Corby P, Bartizek R, Corby A, Coelho M, Costa S, Bretz WAG, Bretz WA. J of Periodont; August 2006,77(8):1386-91.

2. A **Controlled Clinical Study to Determine the Gingivitis Benefit of Flossing.** The University of Texas Health Science Center at San Antonio Dental School, USA. Study conducted in Guatemala. Final Study Report.

3. **Comparative effectiveness of flossing and brushing in reducing interproximal bleeding.** Graves RC, Disney JA, Stamm JW. J of Periodontol; May 1989;60(5): 243-247.

4. **Comparison of the use of different modes of mechanical oral hygiene in prevention of plaque and gingivitis.** Rosema NAM, Timmerman MF, Versteeg PA, van Palenstein Helderman WH, Van der Velden U, Van der Weijden GA. J of Periodontol; August 2008;79(8): 1386-1394.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Silver Spring, MD 20993-0002

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8700 Mason-Montgomery Road
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SEP 24 2009

Re: K091964
Trade/Device Name: Crest Glide Dental Floss
Regulation Number: 872.6390
Regulation Name: Dental Floss
Regulatory Class: I
Product Code: JES
Dated: June 30, 2009
Received: July 1, 2009

Dear Ms. Schofield:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K091964

Device Name: Crest Glide Dental Floss

Indication For Use:

To remove plaque and food particles from between the teeth as part of a comprehensive dental treatment program to reduce tooth decay and to treat and prevent gingivitis.

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Kevin Mulley for NSR

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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