FEB 3 1994 K935440

9.0 510(k) SUMMARY

JOHNSON & JOHNSON Fluoride Dental Floss, Mint Waxed is substantially equivalent to Oral-B Dental Floss with Fluoride, Mint Waxed (K925409) and JOHNSON & JOHNSON Dental Floss, Mint Waxed (Pre-1976 Medical Device Amendment 510(k) exemption). JOHNSON & JOHNSON Fluoride Dental Floss, Mint Waxed can be described as a multifilament 840 denier, Nylon 6 yarn having an initial coating of microcrystalline wax and a final coating of oral secretory fluid soluble polyethylene glycol wax, with the latter coating containing both the flavor component and sodium fluoride. Upon contact with saliva, the polyethylene glycol wax dissolves releasing both flavor and fluoride. Each 18 inches of JOHNSON & JOHNSON Fluoride Dental Floss, Mint Waxed contains on an average 0.15 milligrams of sodium fluoride. However, the primary mode of action of JOHNSON & JOHNSON Fluoride Dental Floss, Mint Waxed is to mechanically remove plaque and food particles from between the teeth, and along and under the gumline. No anticaries drug claims associated with the fluoride coating on JOHNSON & JOHNSON Fluoride Dental Floss will be made. The currently marketed JOHNSON & JOHNSON Dental Floss, Mint Waxed has been clinically proven to remove plaque and food particles from between the teeth, and along and under the gumline. Safety and effectiveness information upon which the substantial equivalence is based will be made available by JOHNSON & JOHNSON Consumer Products, Inc. to interested persons upon request.

The data and information submitted in this 510(k) Premarket Notification is truthful and accurate and no material fact has been omitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 3 1994

Mr. James A. Haviland
Manager, Regulatory Affairs
Johnson and Johnson Consumer Products, Inc.
Grandview Road
Skillman, New Jersey 08558-9418

Re: K935440
Fluoride Dental Floss
Regulatory Class: I
Dated: November 11, 1993
Received: November 12, 1993

Dear Mr. Haviland:

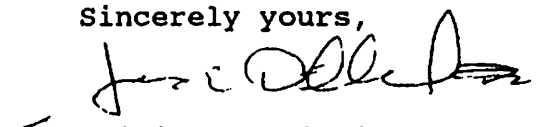
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



For Philip J. Phillips
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health