JAN 28 1993

k925409

510(k) SUMMARY
ORAL-B DENTAL FLOSS WITH FLUORIDE

Oral-B Dental Floss With Fluoride is substantially equivalent to Oral-B Dental Floss. Each 18 inches of Dental Floss with Fluoride contains an average of 0.15 mg. of sodium fluoride, which is recognized as a safe and effective anti-caries agent. However, the primary mode of action of Oral-B Dental Floss With Fluoride is to mechanically remove plaque and food particles from between the teeth. Oral-B Dental Floss has been clinically proven to do this. No oral irritation was observed in animal testing with Oral-B Dental Floss with Fluoride.

Sharon Snyder
Director of Regulatory Affairs
Oral-B Laboratories
October 20, 1992

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JAN 28 1993

Ms. Sharon Snyder
Director, Regulatory Affairs
One Lagoon Drive
Redwood City, California 94065-1561

Re: K925409
ORAL-B DENTAL FLOSS WITH FLUORIDE
Regulatory Class: I
Dated: October 23, 1992
Received: October 26, 1992

Dear Ms. Snyder:

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 Division of

Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. 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 PRB

Paul R. Beninger, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health