Procter&Gamble K973236

*The Procter & Gamble Company*
*Health Care Research Center*
*8700 Mason-Montgomery Road, Mason, Ohio 45040-9462*

MAR 11 1998

**Premarket Notification [510(k)] Summary**
This summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR §807.92(c).

**Submitter's Name, Address and Phone Number**
The Procter & Gamble Company
P.O. Box 599
Cincinnati, Ohio 45202
Phone: (513) 622-2185
Fax: (513) 622-0521
Contact person: Marlene B. Feder
Preparation Date: 8/26/97

**Name of the Device**

| | |
|---|---|
| Trade Name: | Crest Toothbrush with MicroShield |
| Common Name: | Manual Toothbrush |
| Classification Name: | Manual Toothbrush (per 21 CFR §872.6855) |

**Predicate Devices**
This premarket notification is claiming substantial equivalence to Crest Toothbrushes and the Butler G.U.M. Antibacterial Toothbrush (K950993).

**Description of the Device**
The Crest Toothbrush with MicroShield is a manual toothbrush consisting of a shaft with synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay. The toothbrush contains an antimicrobial agent to prevent the growth of bacteria on the brush between uses, maintaining the cleanliness of the brush.

**Intended Use of the Device**
The Crest Toothbrush with MicroShield is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay. The addition of the antimicrobial agent is to prevent the growth of bacteria on the toothbrush between brushings. The antimicrobial treatemnt is not intended to have any effect on the user.

**Comparison of Technological Characteristics**
The Crest Toothbrush with MicroShield is composed of handle and bristle materials identical to other Crest Toothbrushes. Like the Butler G.U.M. Antibacterial Toothbrush (K950993), the Crest Toothbrush with MicroShield contains an antimicrobial agent to prevent the growth of bacteria on the brush between uses. Both the Butler G.U.M. Antibacterial Toothbrush and the contain an antimicrobial ingredient. While the antimicrobial agents in the two brushes are different, the antimicrobial activity of the triclosan containing brush is expected to be, at a minimum, comparable to the antimicrobial activity of chlorhexidine/zinc oxide containing brush.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 1998

Ms. Marlene B. Feder
Manager, Regulatory Affairs
Proctor & Gamble Company
8700 Mason-Montgomery Road
Mason, Ohio 45040-9462

Re: K973236
Trade Name: Crest Toothbrush with Microshield
Regulatory Class: I
Product Code: EFW
Dated: December 19, 1997
Received: December 22, 1997

Dear Ms. Feder:

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 (for the indications for use stated in the enclosure) to 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). 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 (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. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PROCTER & GAMBLE COMPANY
**510(k) Notification**

**Manual Antimicrobial Toothbrush**

**510(k) Number (if known):**

**Device Name:** Crest Toothbrush with MicroShield

**Indications for use:**

To remove adherent plaque and food debris from the teeth to prevent tooth decay.

To prevent the growth of bacterial between brushings to maintain the cleanliness of the toothbrush.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973336

Prescription Use ____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)