JUL 24 1997

K971589

510(k) Summary

Summary	Summarized below is the safety and effectiveness information compiled in support of claims of substantial equivalence (as defined in the FD&C Act).
Submitter	Personal Products Company 199 Grandview Road Skillman, New Jersey 08558
Contact Person	Ms. Lorna-Jane Bremer Senior Regulatory Affairs Associate Johnson & Johnson Consumer Franchises Worldwide 199 Grandview Road, Skillman, New Jersey 08858 Phone: 908-874-1700 Fax: 908-874-2751
Date of Submission	April 29, 1997
Device Trade Name	**REACH®** Antibacterial Toothbrush
Device Common Name	Toothbrush
Device Classification	Manual Toothbrush -- Class I Device (Ref. 21 CFR § 872.6855)
Predicate Device	Butler G.U.M. Antibacterial Toothbrush (John O. Butler), a Class I post-amendments 510(k) device (K950993).
Intended Use	Both the modified device and the predicate device are intended to be used to remove adherent plaque and food debris from the teeth to reduce tooth decay.
Technological Characteristics/ Description	Both the modified device and the predicate device are manual toothbrushes consisting of a shaft with synthetic bristles at one end. Antibacterial agents have been incorporated into the devices.

Performance Data

Johnson & Johnson Consumer Franchises Worldwide has conducted a thorough program to evaluate the safety of the Modified Device. This program consisted of the following:

Bench Testing

1. *Microbiology Study - Zone of Inhibition Test*

The purpose of this study was to evaluate the antibacterial activity of the "plastic" portion of the toothbrush both before and after simulated use. Toothbrushes with antibacterial "plastic" as well as toothbrushes without antibacterial "plastic" were exposed to several different strains of bacteria which may be found on toothbrushes after use. Results showed that the "plastic" portion of the toothbrush with antibacterial agent added was effective in inhibiting the growth of most of the bacteria tested.

2. *Analytical Study - Extraction Study Using HPLC*

The purpose of this study was to determine whether any of the antibacterial agent contained in the toothbrush was able to leach out into a toothpaste/water slurry after 6-hours of simulated brushing and into an alcohol/water solution after soaking the toothbrush for 24 hours. HPLC results showed no detectable antibacterial agent in either the toothpaste/water slurry or the alcohol/water solution (limit of quantitation of antibacterial agent = 1 ppm).

Pre-Clinical Testing

1. *Mucous Membrane Irritation - Hamster Cheek*

The purpose of this study was to evaluate the irritation potential of the toothbrush with added antibacterial agent after it remained in contact with oral mucosal tissue in the hamster cheek pouch for one week. Results showed no significant difference in degree of irritation between toothbrushes with antibacterial agent and toothbrushes without antibacterial agent.

2. *in vitro Cytotoxicity Study - USP Agar Diffusion*

The purpose of this study was to evaluate the biocompatibility of the toothbrush with antibacterial agent added using an *in vitro* mammalian cell culture test based on United States Pharmacopeia (USP) guidelines. Results showed no evidence of cell lysis or toxicity for either the toothbrushes with an added antibacterial agent or the toothbrushes without an added antibacterial agent.

Conclusions

The modification to this device does not raise new types of safety or effectiveness questions. Accepted scientific methods were utilized to assess the effects of the modification. On this basis, we conclude that the data provided demonstrate that the Modified Device is safe for its intended use.

Based on the 510(k) Substantial Equivalence Decision-Making Process review as shown and the testing information provided, we believe that the Modified Device is substantially equivalent to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lorna-Jane Bremer
Senior Regulatory Affairs Associate
Personal Products Company
199 Grandview Road
Skillman, New Jersey 08558

JUL 24 1997

Re: K971589
Trade Name: Reach Antibacterial Toothbrush
Regulatory Class: I
Product Code: EFW
Dated: April 29, 1997
Received: May 1, 1997

Dear Ms. Bremer:

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

INDICATION FOR USE

510(k) Number (if known): K971589

Device Name: REACH® Antibacterial Toothbrush

Indications For Use:

REACH® Antibacterial Toothbrush is used to remove adherent plaque and food debris from teeth to reduce tooth decay. This device is made of a shaft (handle) with synthetic bristles attached at one end. An antibacterial agent has been added to the handle portion. The antibacterial activity is limited to the handle of the toothbrush.

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

(Division Sign-Off) [signature]
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K971589

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use K971589 OR Over-The-Counter-Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)