JUN 0 3 2002

Section E - 510(k) Summary

K 020776

March 5, 2000

Applicant:

CORONET GROUP North America, LLC
175 Dwight Road, Suite 200
Longmeadow, MA 01106
Phone: 413-565-4602 Fax: 413-565-4603

Application Preparer & Correspondent

Thomas E. Ferari
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Proprietary Device Name: Medoral Hygienic Toothbrush with DENTOSAN® Filaments
Common Device Name: Antibacterial Toothbrush Filament
Classification Name: Manual Toothbrush (Class I Device Ref 21CFR 872.6855)

Predicate Devices:

Reach Antibacterial Toothbrush	K971589
Crest Toothbrush with Microshield	K973236
Butler Antibacterial Interdental Toothbrush	K974761

Device Description: The Medoral Hygienic Toothbrush is a toothbrush with DENTOSAN® filaments. The DENTOSAN® filament is a nylon filament impregnated with an anti bacterial agent to prevent the growth of bacteria on and between the filaments after use of the toothbrush.

Intended Use: The Medoral Hygienic Toothbrush is intended for over-the-counter use as a toothbrush. The antibacterial agent maintains the cleanliness of the brush by preventing the growth of bacteria on and between the filaments after use.

Technological Characteristics: The DENTOSAN® filament is impregnated with a high level of silver to prevent the growth of bacteria on or between the toothbrush bristles. The active ingredient is distributed throughout the nylon filament and provides long lasting antimicrobial action.

Substantial Equivalence Assessment: All of the predicate devices are toothbrushes with antibacterial ingredients incorporated into them. Although the antibacterial agents (triclosan and chlorhexidine/zinc oxide) are different, in the predicate devices, their effect is comparable to the silver used in the DENTOSAN® filament. The effect of the antimicrobial agent was tested and found to be effective using worst case testing for useful life, simulated use extraction testing and antimicrobial effectivity. Additionally, the filament was determined to be biocompatible using the methods recommended in ISO 10993 Biological Testing of Medical and Dental Materials and Devices.

Summary:
The antimicrobial agent used is the DENTOSAN® filament does not raise any new safety or effectiveness concerns. The biocompatibility and effectiveness of the antibacterial agent was tested using established scientific methods and test protocols. Therefore, the Medoral Hygienic Toothbrush with DENTOSAN® filaments is believed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2002

C/O Mr. Thomas E. Ferari
Medical Device Consultant
Coronet Group North America, LLC
181 Dixion Road
Queensbury, New York 12804

Re: K020776
Trade/Device Name: Medoral Hygienic Toothbrush with DENTOSAN® Filaments
Regulation Number: 872.6855
Regulation Name: Toothbrush with Antibacterial Filament
Regulatory Class: I
Product Code: EFW
Dated: March 5, 2002
Received: March 11, 2002

Dear Mr. Ferari

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613dditionally, 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Rebecca Cucerite for

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

Enclosure

K 020776

Section D - Statement of Indications for Use

510(k) Number: TBD

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175 Dwight Road, Suite 200
Longmeadow, MA 01106
Phone: 413-565-4602 Fax: 413-565-4603

Proprietary Device Name: Medoral Hygienic Toothbrush with DENTOSAN® Filaments

Intended Use: The Medoral Hygienic Toothbrush with DENTOSAN® Filaments is a toothbrush to remove plaque and debris from the teeth and prevent tooth decay. The antibacterial agent impregnated in the filament kills bacteria and prevents their growth on and between the bristles after and between uses.

for Dr Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020776