JUL 17 2002

K021383

G. 510(k) Summary of Safety and Effectiveness Information

Company Information:

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Contact: Paul C. Ford, P.E.
Director of Regulatory Affairs

Summary Preparation Date: April 30, 2002

Device Information:

Classification Panel: Dental Devices

Trade Name: Zeodyne Toothbrush with AgION ™ Antimicrobial

Common Name: Toothbrush

Classification Name: Toothbrush, Manual

Regulation Number: 21 CFR § 872.6855

Product Code: EFW

Predicate Device:

Device Name	Applicant Name	510(k) Number
Crest Toothbrush with MicroShield	The Proctor & Gamble Company	K973236
Disposable Stethoscope Diaphragm with AgION Antimicrobial Compound	Doctor's Research Group	K002047

Device Description:

The Zeodyne Toothbrush with AgION antimicrobial 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. 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:

The Zeodyne Toothbrush with AgION™ Antimicrobial is intended to remove adherent plaque and food debris from the teeth. The addition of the antimicrobial agent is to prevent the growth of bacteria on the toothbrush between brushings. The antimicrobial treatment is not intended to have any effect on the user.

Technological Characteristics Compared to the Predicate Devices:

But for the antimicrobial additive, the Zeodyne Toothbrush with AgION antimicrobial is composed of handle and bristle materials similar to the Crest toothbrush. Like the Crest Toothbrush with MicroShield, the Zeodyne Toothbrush with AgION antimicrobial contains an antimicrobial agent to prevent the growth of bacteria on the brush between uses. Both the Crest Toothbrush with MicroShield and the Zeodyne Toothbrush with AgION antimicrobial contain an antimicrobial ingredient. While the antimicrobial agents in the two brushes are different, the antimicrobial activity of the Crest antimicrobial brush, which contains a chlorhexidine/zinc oxide antimicrobial is expected to be, at a minimum, comparable to the antimicrobial activity of Zeodyne Toothbrush with AgION antimicrobial which contains silver zeolite.

Conclusions of Non Clinical Tests:

Laboratory studies for plastic bristle fibers containing AgION antimicrobial have shown that the product reduces the growth of bacteria on the surface of the fiber.

H. Description

The Zeodyne Toothbrush with AgION antimicrobial consists of a polymer based handle and either Nylon 6-12 or polybutylene terephthalate (PBT) bristles. The bristles contain 0.5% AgION antimicrobial.

The antimicrobial has been demonstrated to reduce the growth of bacteria and is registered with the United States Environmental Protection Agency as a bacteriostat. The EPA registered the antimicrobial under the manufacturer's name, Sinanen Company, Limited. The manufacturer has issued a Notice of Supplemental Distribution of a Registered Pesticide Product to AgION Technologies, LLC. (See Appendix 3 & 4)

The antimicrobial is the distinguishing attribute, which is the basis for this 510(k) notification.

A risk assessment, Evaluation of the Potential Health Risks Associated with Zeomic® Type AJ10D Silver Zeolite A - Impregnated Articles: Toothbrushes and Toys was prepared to support the addition of toothbrushes to the current EPA label. This assessment demonstrates the safety of the product by calculating the exposure and comparing it to the EPA Reference Dose. Exposure is calculated at 2.4×10^{-5} which as a percentage of the EPA RfD (5 ug/kg/day) is 0.0005. The full evaluation is provided in Appendix 5.

Argyria is a cosmetic effect in which the skin is discolored; it does not impair body function. Silver is currently used in many home water treatment devices. EPA investigated this effect in establishing the National Secondary Drinking Water Regulations, see Federal Register Vol. 56, No. 20 pp. 3526, 3573-3574 in Appendix 6. The Federal Register notice describes EPA's Derivation of a Cosmetic Reference Dose for silver. The Cosmetic RfD is calculated to be 4.7 ug Ag/kg/day and is significantly greater than the anticipated exposure of 2.4×10^{-5} ug/kg/day. No cosmetic effects are expected from the use of the Zeodyne toothbrush.

Background on the AgION Antimicrobial Compound:

Synthesis of the Antimicrobial:

The AgION antimicrobial additive is manufactured from a solution of aluminum hydroxide and sodium silicate. The zeolite is formed in a highly controlled crystalline process. The powder is then separated and washed to remove any residual electrolytes. The zeolite is then added to the ion exchange solution, which incorporates the Ag, Zn and ammonium. The AgION powder is then separated from the solution and dried before packaging. High purity, media-free milling can be used to reduce the particle size. The entire process is complete in a closed system, through to the drying stage.

Compounding:

Incorporation in the Nylon 6-12 or PBT is achieved by first preparing a masterbatch of the polymer. The antimicrobial is compounded into a polymer matrix to yield master batch at a load level of 60% by weight. Preparation of the polymer master batch is carried out with a twin-screw extruder having a Length/Diameter (L/D) ratio of 32:1. The carrier resin is dried to moisture content of 0.010 percent or less using a regenerating desiccant-type, dehumidifying dryer. The extrudate must remain completely free of moisture via an in-line drying system for master batch pellet conditioning.

The antimicrobial, base polymer and master batch must be maintained under conditions of maximum dryness throughout storage, handling (pre- and post process) and material feeding. All feed hoppers and holding bins, including the collection vessel for master batch pellets, are blanketed with dry air.

Packaging / Storage / Shipping:

When master batch compounding is completed, the master batch is immediately sealed in the holding vessel and allowed to cool. The storage has a liner with sealing capability and a Water Vapor Transmission Rate (WVTR) not to exceed 0.000 g/in^2/24hr. (e.g. foil-lined, metalized Mylar®), and blanketed with dry air. The masterbatch is stored in a temperature-stable, dry location, between 15-25°C (60-80°F) and <40% relative humidity.

Processing:

The bristle specifications are for a load level of 0.5% antimicrobial.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Mr. Paul C. Ford
Director of Regulatory Affairs
AgION Technologies, LLC
60 Audubon Road
Wakefield, Massachusetts 01880

Re: K021383
Trade/Device Name: Zeodyne™ Toothbrush with AgION™ Antimicrobial
Regulation Number: 872.6855
Regulation Name: Manual Toothbrush
Regulatory Class: I
Product Code: EFW
Dated: April 30, 2002
Received: May 2, 2002

Dear Mr. Ford:

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) 594-4613. 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" (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,

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

Enclosure

I. Statement of Indication For Use

U.S. Food and Drug Administration - Center for Devices and Radiological Health

510(k) Number (if known): _____

Device Name: Zeodyne™ Toothbrush with AgION™ Antimicrobial

Indications for Use:

The Zeodyne Toothbrush with AgION™ Antimicrobial is intended to remove adherent plaque and food debris from the teeth. The addition of the antimicrobial agent is to prevent the growth of bacteria on the toothbrush between brushings. The antimicrobial treatment is not intended to have any effect on the user.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021383

(Optional Format 3-10-98)