K061351

510(k) SUMMARY

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JUN - 5 2006

Applicant:

Braun GmbH
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Application Correspondent:

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Date summary prepared: January 6, 2006

Proprietary name of device: Oral-B® Sonic Complete™

Generic/classification name: Toothbrush, Powered

Product code (classification): JEQ (Class 1, 21 C.F.R. 872.6865)

Legally Marketed Predicate Devices:

- Sonicare® Advance Toothbrush (K040416)
  Philips Oral Healthcare, Inc.

- Oral-B® Sonic Complete™
  Braun GmbH

Device Description and Technological Characteristics:

Oral-B® Sonic Complete™ is a rechargeable electric toothbrush comprised of a charging unit and a rechargeable power handle. The rechargeable power unit is inductively charged and therefore electrically safe in accordance with the Second Edition of the standard for Personal Hygiene and Health Care appliances, UL 1431. The Oral-B® Sonic Complete™ electric toothbrush has a vibrating brush head that moves with a side-to-side movement. The brush head is designed to facilitate deeper penetration of interdental areas. The brush head moves side-to-side along the axis of the brush head at 260 Hz at an unloaded angle of ± 5 degrees. The brush head has no moving parts and is similar to a manual brush.

The Oral-B® Sonic Complete™ has a longitudinal brush head with a length of 22 mm and a width of a 9mm. The tufts are angled in 3 directions. The inner row with oval tufts and the outer rows are angled in opposite directions at an angle of 7.5 degrees. In addition, the outer rows are angled outwards for improved gumline cleaning at an angle of 5 degrees. The bristles are standard nylon filaments with a diameter of 6 and 6.5 mil. Two rows of bristles are longer and form a power tip for improved interproximal cleaning. These power tips have a wear indicator function and are colored with the FDA approved colorant FD&C blue No.2. The bristle material is Polyamid or PA6.12.

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510(k) SUMMARY Cont'd

The Oral-B® Sonic Complete™ features a Pressure Control to help avoid possible gingival damage by users who apply excessive pressure during brushing; the drive system and the soft bristles are designed so that the bristle tip movement dramatically decreases to almost zero at applied loads above 2 N. It also features a Professional Timer and a Push-Push switch. The Professional Timer automatically interrupts the brushing motion briefly with a short stuttering sound every 30 seconds to remind the user to move to another quadrant of the mouth, so that each quadrant is brushed equally. At the moment we only have a "stuttering timer" as described, however there soon will be a version sounding a "beeping noise" after 2 minutes brushing time. Oral-B® Sonic Complete™ offers customized brushing modes for complete mouth care. The basic model offers two modes and the deluxe model offers three modes controlled by the Push-Push switch: ***Clean:*** for a complete cleaning of your teeth and gums, ***Soft:*** for the gentle care of your tongue and other sensitive areas, and ***Massage:*** *(deluxe model only)* for a gentle stimulation of gums. The toothbrush features a round handle with anti-slip characteristics for better control in wet conditions.

While power toothbrushes are 510(k) exempt device, we believe the expanded indication for use of treating and preventing gingivitis may exceed the limitation for 510(k) exemption. The expanded indications for use (i.e., treating and preventing gingivitis) are the only changes from the currently marketed device Oral-B® Sonic Complete™. There are no changes to the design, materials or manufacturing process of this device.

Indications for Use:
To promote good oral hygiene, including plaque removal and treating and preventing gingivitis.

Testing:

Oral-B® ® Sonic Complete™ powered toothbrush has been tested in numerous controlled clinical studies. These trials evaluated oral soft and hard tissue for safety, plaque, gingivitis and bleeding. Collectively, these studies demonstrate that the Oral-B® Sonic Complete™ powered toothbrush is effective at treating and preventing gingivitis.

Quality assurance testing on the Oral-B® Sonic Complete™ electric toothbrush has been conducted to ensure the integrity of products.

Oral-B® Sonic Complete™ product is a rechargeable battery operated toothbrush. The toothbrush handle is inductively charged so there is no electrical connection between the charger and handle. All electrical components are housed within thermoplastic enclosures and the product is provided with a Listed 1flexible supply cord terminating in a parallel blade attachment plug for connection to a nominal 100-120 V, 50-60 Hz supply source.

Oral-B® Sonic Complete™ products are evaluated and comply with the applicable requirements to bear the Underwriters Laboratories Inc. Mark (UL 1431).

Conclusions:

The results from these tests support the safety and effectiveness of Oral-B® Sonic Complete™ power toothbrush and its substantial equivalence to the predicate device without raising new safety or effectiveness issues.

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Bibliography

1. M.J. Cronin, W.Z. Dembling, M.A. Cugini, ; A 90 Day Clinical Comparison of the Safety and Efficacy of Two Toothbrushes, Final report: Study Number 01 16 04 03, Date of Report: April 5, 2004, New Institutional Service Co., Inc., Dental Research and Product Testing , Northfield, New Jersey

2. N.A.M Rosema, M.F. Timmerman, M. Fiscaer, P.A. Versteeg, U. Van Der Velden, G.A. Van Der Weijden. ; Healing Effect of Experimental Gingivitis Using 2 Sonic Toothbrushes. Department of Periodontology, Academic Centre for Dentistry Amsterdam, 6 April 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2006

Braun GmbH
C/O Ms. Amanda Heffernan
The Gillette Company
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Boston, Massachusetts 02199-8004

Re: K061351
Trade/Device Name: Oral-B® Sonic Complete™
Regulation Number: 21 CFR 872.6865
Regulation Name: Powered Toothbrush
Regulatory Class: I
Product Code: JEQ
Dated: May 11, 2006
Received: May 15, 2006

Dear Ms. Heffernan:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K061351

Indications for Use

510(k) Number (if known): _____

Device Name: **Oral-B® Sonic Complete™**

Indications for Use: To promote good oral hygiene including plaque removal and treating and preventing gingivitis.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...n Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number K061351