MAY 1 0 2002

K021258

8.0 510(k) Summary

Submitted by:	David Link, Vice President EXPERTech Associates, Inc. 100 Main Street, Suite 120 Phone (978) 371-0066 Fax (978) 371-1676
Date of summary	April 30, 2002
Device name	Germ Terminator Toothbrush Sanitizer
Common name	Toothbrush Sanitizer
Classification name	Toothbrush, Manual
Predicate device	The subject device is substantially equivalent to the Otres Toothbrush Sanitizer (K003517).
Description	The Germ Terminator uses steam heat to sanitize two manual toothbrushes or two toothbrush heads. Water is poured into a reservoir in the device's housing and it is heated to its boiling point. Water is thereby converted into steam, which sanitizes the toothbrushes in the housing. The steam cycle is followed by a drying cycle. Testing demonstrated that the toothbrushes treated in the Germ Terminator were sanitized.
Intended use	The Germ Terminator is designed to sanitize up to two manual toothbrushes or two toothbrush heads between uses. The Germ Terminator is intended for over the counter use.
Technological Characteristics	The subject device sanitizes by means of steam heat and the predicate device sanitizes by means of activated oxygen (ozone).
Testing	Laboratory testing demonstrated that toothbrushes treated in the Germ Terminator are effectively sanitized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2002

Germ Terminator Corporation
Mr. Donald J. Sherratt
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K021258
Trade/Device Name: Germ Terminator GT 100 Toothbrush Sanitizer
Regulation Number: 872.6855
Regulation Name: Toothbrush, Manual
Regulatory Class: I
Product Code: MCF
Dated: May 2, 2002
Received: May 3, 2002

Dear Mr. Sherratt:

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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Germ Terminator Toothbrush Sanitizer

Indications For Use:

The Germ Terminator Toothbrush Sanitizer is designed to sanitize up to two manual toothbrushes or two toothbrush heads between uses.

The Germ Terminator Toothbrush Sanitizer is intended for home use and will be available "over the counter."

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF 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 K021255

Prescription Use_____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**