



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Mr. Brad Downs
Senior Vice President
Sterisil
200 South Wilcox #417
Castle Rock, Colorado 80104

Re: K031681

Trade/Device Name: Sterisil® Antimicrobial Tubing and Bottle
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: October 02, 2003
Received: October 03, 2003

Dear Mr. Downs:

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. In particular, please note that many water treatment products, such as your device, are also regulated by the Environmental Protection Agency's (EPA) Office of Pesticide Programs. You may wish to consult with EPA to determine if registration with the agency is necessary for your device. Regarding FDA, 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 (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) you may obtain. 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,



Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



22. Indications for Use

510(k) Number (if known): K031681

Device Name: Dental Operative Unit Antimicrobial Bottle and Tubing

Indications for Use: "The treated article controls the growth of bacteria, fungus, and algae providing the antimicrobial surface is regenerated with the continuous use of a Sterisil water pre-treatment product. The Sterisil treated article is intended to be used with distilled, deionized, or reverse osmosis water. Efficacy for tap water has not been determined. This product is not intended to provide sterile water."

A handwritten signature in cursive script, appearing to read "Susan Guover".

(Division Signatory)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031681

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

Concurrence of CDRH, Office of Device Evaluation (ODE)