



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 30 2008

Ms. Linda Nelson  
Regulatory Affairs Manager  
Steritec Products Manufacturing Company, Incorporated  
599 Topeka Way, Suite 400  
Castle Rock, Colorado 80109

Re: K072408

Trade/Device Name: Emu-Graph Emulator, Model No.: CI 131  
Regulation Number: 880.2800  
Regulation Name: Sterilization Process Indicator  
Regulatory Class: II  
Product Code: JOJ  
Dated: April 10, 2008  
Received: April 14, 2008

Dear Ms. Nelson:

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.

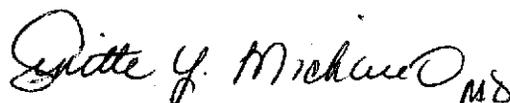
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Chiu Lin, Ph.D." with a stylized flourish at the end.

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

**Indications for Use**

510(k) Number (if known): K072408

Device Name: Emu-Graph Emulator, Model No.: CI 131

**Indications for Use:**

SteriTec Emu-Graph is a steam sterilization emulator for use in a pre-vacuum steam sterilization process operating at 132°C (270° F) or 135° C (275° F). When exposed to steam sterilization conditions both the 2 MIN and 4 MIN indicator bars will turn from purple to green giving an integrated response and visible indication that sterilization conditions were met. If only the 2 MIN indicator bar turns green and the 4 MIN indicator bar displays an incomplete color change, insufficient sterilization conditions occurred.

Critical Parameters in a standard hospital pre-vacuum steam sterilizer

Temperature	4 MIN Indicator
132°C (270°F)	4 minutes
135°C (275°F)	3 minutes

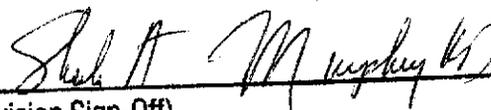
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

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)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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510(k) Number:   K 072 40 8