



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 1999

Mr. Thomas R. Gunerman
Intersurgical Incorporated
417 Electronics Parkway
Liverpool, NY 13088-6098

Re: K990949
Clear-Therm HMEF - PN 1841, Clear-Therm HMEF w/Flextube - PN
1841-T, Clear-Guard II Filter PN - 1844, and Clear-Guard II
Filter w/CO2 Monitoring Port - PN 1844-P
Regulatory Class: II (two)
Product Code: CAH
Dated: March 16, 1999
Received: March 22, 1999

Dear Mr. Gunerman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Appendix I. Indication For Use

510(k) Number (if known): 2990949

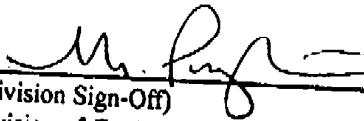
Device Name: 1844 Clear-Guard II Filter
1844-P Clear-Guard II with CO2 Monitoring Port
1841 Clear-Therm HMEF
1841-T Clear-Therm HMEF with Flextube

Indications For Use:

1844 & 1844-P: For use at the equipment connection. Designed to reduce bacterial/viral transmission to and from patient, equipment and environment. CAUTIONS: When used in the exhalation limb in conjunction with a water bath humidifier, a water trap should be placed between the filter and the patient; 1841 & 1841-T: For use at the patient connection. Designed to reduce bacterial/viral transmission and to reduce the loss of patient heat and humidity. CAUTIONS: This product is not suitable for patients with thick or copious secretions; Do not use this product in conjunction with other humidification sources. 1844, 1844-P, 1841, 1841-T: ISO connections: When assembling any connections use a push and twist action to ensure a secure fit. Single patient use. Non conductive. Non sterile. Do not autoclave. CAUTIONS: Never position any filter on the inspiratory limb downstream of a water bath humidifier; Do not use this product between the patient and a source of nebulized drugs; When nebulized drugs are administered, resistance should be monitored and the product should be exchanged following standard hospital procedure; All ports should remain capped when not in use; Replace every 24 hours or more frequently if visible deterioration is observed, following standard hospital procedure; Federal law restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ☒
(Per 21 CFR 801.109)

or Over-The-Counter Use _____

(Optional Format 1-2-96)