



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 9 2001

Mr. Charles A. Burt  
King Systems Corporation  
15011 Herriman Boulevard  
Noblesville, IN 46060

Re: K012485  
MS-140 All Round® Enhanced Performance Filter  
MS-141 All Round® Enhanced Performance Filter Angled  
MS-142 All Round® HME/ Enhanced Performance Filter  
MS-143 All Round® HME/ Enhanced Performance Filter Angled  
Regulation Number: 868.5260  
Regulation Name: Breathing Circuit Bacterial Filter  
Regulatory Class: II (two)  
Product Code: 73 CAH  
Dated: July 30, 2001  
Received: August 2, 2001

Dear Mr. Burt:

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.

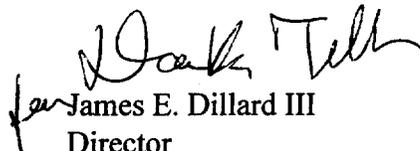
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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) 594-4646. 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,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section #3**

Device name: K012485  
MS-140 All-Round® Enhanced Performance Filter  
MS-141 All-Round® Enhanced Performance Filter Angled  
MS-142 All-Round® HME / Enhanced Performance Filter  
MS-143 All-Round® HME / Enhanced Performance Filter Angled

**Intended Use:**

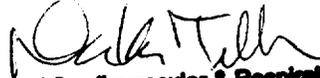
1. A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases of a breathing circuit.
2. A heat and moisture exchanger (HME) is a device intended to be positioned over a tracheotomy or tracheal tube to warm and humidify by passive means gases breathed in by a patient during anesthesia or ventilator care.
3. Each All-Round® filter or HME/filter is intended for adult patients whose respiratory status will not be compromised by the dead space.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 868.5260)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K012485