Identification of the Device:
Proprietary-Trade Name: Med Systems Electro Flo Percussor Model 5000
Classification Name: Powered Chest Percussor Product Code BYI
Common/Usual Name: Powered Chest Percussor

Equivalent legally marketed devices: This product is similar in function to the Model 2500 “Fluid Flo" percussor that our company has manufactured for hospitals since 10-23-82 under 510(k) number K802399. (Company formerly known as Medical Equipment Development Co., Inc.) as well as PURITAN BENNETT McSHIRLEY K801982 and SOUTHWEST MEDICAL MFG. INC (STROM) K821265, K821570 K813438

Indications for Use (intended use): The intended use of the Med Systems Electro Flo Percussor Model 5000 is provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy (1) (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Med Systems Electro Flo Percussor Model 5000 is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.


Description of the Device: The Model 5000 “Electro Flo” Percussor is just an electrically cycled hammer. It has the exact same function and operation as the Model 2500 “Fluid Flo" percussor that our company has manufactured for hospitals since 10-23-82 under 510(k) number K802399. The “Fluid Flo" percussor is cycled by an oscillating pneumatic valve whereas the “Electro Flo” percussor is cycled electronically.
### 5. Substantial Equivalence Chart

<table>
<thead>
<tr>
<th>Feature</th>
<th>Med Systems 2500 Fluid Flo K802399</th>
<th>PURITAN BENNETT McSHIRLEY K801982</th>
<th>SOUTHWEST MEDICAL MFG. INC STROM K821265, K821570 K813438</th>
<th>Med Systems 5000 Electro Flo (This submission)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDICATION For USE</td>
<td>For respiratory secretion clearance for COPD, cystic fibrosis, emphysema, atelectasis and other obstructive lung conditions</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
</tr>
<tr>
<td>Power and Control</td>
<td>Pneumatic Solenoid</td>
<td>Electric Solenoid</td>
<td>Electric Motor</td>
<td>Electronic Solenoid</td>
</tr>
<tr>
<td>Speed</td>
<td>5 to 15 Hz</td>
<td>6 to 60 Hz</td>
<td>5 to 60 Hz</td>
<td>5 to 25 Hz</td>
</tr>
<tr>
<td>Weight</td>
<td>1.5 pounds</td>
<td>3 pounds</td>
<td>5 pounds</td>
<td>1.5 pounds</td>
</tr>
<tr>
<td>Energy source</td>
<td>Pneumatic</td>
<td>120 v 60 Hz AC</td>
<td>120 v 60 Hz AC</td>
<td>120 v 60 Hz AC</td>
</tr>
</tbody>
</table>

### 6. Conclusion

After analyzing bench and electrical safety testing data, it is the conclusion of MED Systems that the Med Systems Electro Flo Percussor Model 5000 is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.
MED Systems
C/O Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K031876
Trade/Device Name: Electro Flo Percussor, Model 5000
Regulation Number: 21 CFR 868.5665
Regulation Name: Percussor, Powered-Electric
Regulation Class: II
Product Code: BY1
Dated: August 20, 2003
Received: August 25, 2003

Dear Mr. Kamm:

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 (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.html

Sincerely yours,

[Signature]
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
j) Indications for Use

Device Name: Med Systems Electro Flo Percussor Model 5000

Indications for Use:
The intended use of the Med Systems Electro Flo Percussor Model 5000 is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy (1) (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Med Systems Electro Flo Percussor Model 5000 is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.