



APR - 7 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Premco Medical Systems, Inc.  
% Underwriters Laboratories, Inc.  
Mr. Jeff D. Rongero  
12 Laboratory Drive  
Research Triangle Park, North Carolina 27709

Re: K082415

Trade/Device Name: Prodigy™ NPWT System, Model: Prodigy™ 800V  
Regulation Number: 21 CFR 878.4780  
Regulation Name: Powered Suction Pump  
Regulatory Class: II  
Product Code: OMP  
Dated: November 10, 2008  
Received: November 12, 2008

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of November 25, 2008.

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 (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 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

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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 continue 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## Section 5. Indications for Use Statement

510(k) number: (to be assigned)

Device Name: Prodigy™ NPWT System, Model: Prodigy™ 800V

### Indications for Use:

The Prodigy™ 800V NPWT System is indicated for use in patients that would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from a patients airway or respiratory support system either during surgery or at the patients bedside.

Prescription Use: Yes and/or Over the Counter Use: No  
(Part 21 CFR 801 Subparts D) (21 CFR 801 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K082415