K122627

18.0 510(k) Summary

In accordance with 21 CFR section 807.92 Hsiner is submitting the following 510(k) summary.

Date: 08/21/2012

18.1 Submitter Information

GaleMed Corporation
87 Li-gong 2nd Road, Wu-Jia, I-Lan, Taiwan 268
Contact Person: Alvin Lee
Tel: + 886 3 990 8618
Fax: + 886 3 990 8245

AUG 2 2 2013

Owner/Operator Number: 8043316

18.2 Name of Device

Proprietary Names: Gio Digital Pressure Monometer
Common Name: Monitor, Airway Pressure
Classification Name: monitor, airway pressure (includes gauge and/or alarm)

Product Code: CAP

Regulation Number: 868.2600

Device Class 2

18.3 Substantially equivalent to:

The Gio Digital Monometer is equivalent to Respironics' pressure manometer (K904935). Other related predicate device:

510(k)	Device Name	Type	Pressure Ranges
K08178	NS Series Airway Pressure Monitors	Balanced Spring	0 - 60 cm H2O
K992101	Criterion 40	Digital Manometer	5 – 99 cm H2O
K110119	NF-009 Pressure Manometer	Balanced Spring	-20 to 80 cmH2O

18.4 Comparison to Predicate Devices

- Both devices use pressure sensor and displays the pressure reading digitally on an LCD screen.
- Pressure measuring ranges differ. The Gio Digital Pressure Monometer is available in four different measuring ranges.
- Display units differ. The Gio Digital Pressure Monometer provides the option to displaying valued in three different units of pressure.

Design, Materials and Intended Use

The Gio Digital Monometer, principles of operation and intended use are essentially equivalent to the predicate device already cleared by FDA.

18.5 Description of the device

The Gio Digital Manometer is light, portable, accurate and can be operate by one hand, monitoring airway pressure during respiratory care. The digital display facilitates easy reading of the pressure value. The manometer displays pressure values on the front panel both digitally and on an analog bar scale. The Gio Digital Manometer also provides a function that display peak pressure when the right button is pressed and the P&H function is activated.

The Gio Digital Manometers are available in four different pressure ranges. All four manometers utilize the same mechanism and only differ in their pressure detecting ranges. Each device is easily recognized by their colors (see Figure 1). All four manometers utilize the same mechanism and only differ in their pressure detecting ranges.

 Gio 1	 Gio 2	 Gio 3	 Gio 4
Color Pink	**Color Blue**	**Color Purple**	**Color Turquoise**
Pressure Range 0 to 30 cmH_2O	**Pressure Range 0 to 80 cmH_2O**	**Pressure Range -30 to 100 cmH_2O**	**Pressure Range -60 to 0 cmH_2O**

Figure 8

Intentionally Left Blank

18.6 Technology

Both the Gio Digital Manometer and the predicate (K904935), convert a signal from a pressure transducer into a signal that is displayed on the LCD panel as a digital pressure value.

18.7 Intended Use of the Device:

The Gio Digital Manometer is intended for used on all patient populations to measure airway pressure in respiratory care devices used in the hospital, and post hospital environments. It may be attached by flexible tubing to devices e.g. resuscitation bags; hyperinflation bags, CPAP Masks or Circuits.

18.8 Performance Summary

- Meets ISO 60601-1 requirements for battery powered equipment
- Accuracy is within ± 0.4 of reading.

18.9 Conclusion

Performance evaluation concludes that the Gio Digital Monometer meet the requirements of IEC 60601-1 associated with battery powered equipment. The Gio Digital Monometer has similar intended use, patient populations and environment of use and equivalent performance to the predicate device.

Attachment A

- **Test Report 1106005001 "IEC/EN 60601-1 Medical electrical equipment"**
- **Test Report T110603212-E "CE EMC Test Report for Digital pressure meter Model GB30**
- **Test Report 101004 "Measurement accuracy test"**

Deliberately Left Blank

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

GaleMed Corporation
C/O Mr. Tom Shanks
MDVentures
29201 Via Norte
TEMECULA CA 92591

Re: K122627
Trade/Device Name: Gio Digital Monometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: August 13, 2013
Received: August 20, 2013

Dear Mr. Shanks:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Indications for Use Statement

510(k) Number: K122627

Device Name: Gio Digital Monometer

Indications for Use:

The Gio Digital Manometer is intended for used on all patient populations to measure airway pressure in respiratory care devices used in the hospital, and post hospital environments. It may be attached by flexible tubing to devices e.g. resuscitation bags; hyperinflation bags, CPAP Masks or Circuits.

Prescription Use __X__ **or** **Over-the-counter use** _____

(Part 21 CFR 801 Subparts D) (21 CFR 807 Subpart C)

Lester W. Schultheis Jr
2013.08.22 14:29:41 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: ___K122627_____