

APR 14 2014

510(k) Summary

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12-Feb-14

Galedmed Corp.
 Amoy Export Processing Zone, 39
 Section 3, Haijing East Road
 Xiamen, Fujian Province, China

Official Contact: Enhe Liu, QA Director

Proprietary or Trade Name: Disposable Adjustable PEEP Valve

Common/Usual Name: PEEP Valve

Classification Name: BYE - Attachment, breathing, positive end expiratory pressure
 21 CFR 868.5965

Predicate Devices: K082092 – Galedmed PEEP valve
 K081266 – Mercury Medical – PEEP Valve MR

Device Description

The proposed Galedmed Disposable Adjustable PEEP valves are identical to their predicate PEEP Valves, K082092, except we have replaced some components that were magnetic with non-magnetic material in order to meet the requirements for MR conditional environments of use. Otherwise the PEEP valves are identical.

Galedmed disposable adjustable PEEP valves elevate the pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

The Galedmed disposable adjustable PEEP valve for use in MR environments is identical to our predicate, K082092, disposable PEEP valve, except we have replaced the materials in 2 components, a push rod and the springs to materials which are less magnetic. Other than these 2 changes, the device is identical to the predicate. These changes / modifications have been evaluated and demonstrated that they do not alter nor change the performance or safety profile of the new device as compared to the predicates.

Modifications to Proposed Device compared to Predicate

The proposed Galedmed Disposable Adjustable PEEP valves are identical to their predicate PEEP Valves, K082092, except we have replaced some components that were magnetic with non-magnetic material in order to meet the requirements for MR conditional environment of use. Otherwise the PEEP valves are identical.

Indications for Use

Single patient use adjustable positive end expiratory pressure (PEEP) valves for use in hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.
 For use with neonates to adults.

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Environment of Use

Hospital, extended care facilities, emergency medical services, and patient transport

May be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Contraindications

Contraindicated in individuals not requiring elevated end expiratory pressure therapy

Predicate Device Comparison:

The proposed disposable adjustable PEEP valves are identical to our predicate Galemed PEEP valves, K082092, except for a change in materials for the rod and the springs to less magnetic materials.

Comparative **Table 1** discusses the major features of the proposed device and the legally marketed predicate device.

The Galemed Disposable Adjustable PEEP Valve is viewed as substantially equivalent to the predicate device based upon the following:

Indications –

- Indicated as a Single patient use adjustable positive end expiratory pressure (PEEP) valve for use in hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.

Discussion – The indications for use are identical for the proposed and predicate device, Galemed PEEP Valve, K082092.

- The addition of the indications for use in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field is new but testing has demonstrated that the device meets the recognized standard as a MR conditional device.

Discussion – The indications for use as MR Conditional is identical for the proposed and predicate device, Mercury Medical, PEEP Valve, K081266.

Technology –

- The technology of the use as a, spring actuated valve, which when placed into a circuit or manual resuscitator, provides positive end expiratory pressure for the patient is identical to the predicates.

Discussion – There are no differences in technology between the proposed device and the predicates - Galemed PEEP Valve, K082092 and Mercury Medical, PEEP Valve, K081266.

Materials –

- The materials are identical to predicate with the exception of a change in the spring material.

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- According to ISO 10993-1 the proposed device would be considered External communicating, Tissue / mucosal, limited duration (< 24 hr)
- Stainless steel is well understood and no addition biocompatibility testing is required for this specific application of the material.

Discussion: We are utilizing identical materials to our predicate - Galemed PEEP Valve, K082092. The differences in the spring material or the rod do not affect performance nor raise any new safety concerns.

Environment of Use –

- Hospital, extended care facilities, emergency medical services, and patient transport and MR suites to 3 Tesla.

Discussion - The environment of use are identical between the proposed device and the predicates - Galemed PEEP Valve, K082092 and Mercury Medical, PEEP Valve, K081266.

Non-clinical Testing -

We have performed the following performance data and testing:

- MR conditional in accordance with ASTM F2052-02 in a 3 Tesla MR suite
 - According to ASTM F2052-02 the proposed device should not deflect more than 45 degree, the proposed device did not deflect this far and thus met the requirements.
- Leakage
 - The device was pressurized and leakage measured before and after age testing. It met the pass /fail criteria
- Pressure / Resistance Accuracy
 - The device was tested for repeatability and accuracy after being subjected to a number of conditions; it met its performance specifications criteria.
- Drop test
 - The device was dropped and tested for leakage and pressure / resistance. It met the pass /fail criteria.
- Environmental Conditions
 - The device was subjected to high and low temperature conditions and then tested, it met its performance specifications criteria.
- Transportation
 - The device was subjected to transportation testing and then tested it met its performance specifications criteria.
- Age testing
 - The device was age testing and then evaluated it met its performance specifications criteria.

Discussion - The performance testing when compared to the predicates - Galemed PEEP Valve, K082092 and Mercury Medical, PEEP Valve, K081266 (for MR conditional environments) support the conclusion of substantial equivalence.

Substantial Equivalence Conclusion -

The sponsor believes that the testing and comparative data presented in the 510(k) supports our claim of substantially equivalence to the identified predicate devices, listed above.

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Table 1 – Comparative Table

Features	Predicate Galemmed PEEP Valves - K082092	Proposed Disposable Adjustable PEEP Valve
Indications for use	Single patient use adjustable positive end expiratory pressure (PEEP) valves for use in hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.	Single patient use adjustable positive end expiratory pressure (PEEP) valves for use in hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions. For use with neonates to adults. Environment of Use: Hospital, extended care facilities, emergency medical services, and patient transport. May be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.
MR Conditional	Mercury Medical PEEP Valve, K081266 May be used in a Magnetic Resonance (MR) environment, not to exceed a 1.5 Tesla or less. Spatial gradient of 450 gauss/cm or less.	May be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla. Spatial gradient of 720 gauss/cm or less.
Patient Use / Duration if use	Single patient use, disposable, < 24 hours	Single patient use, disposable, < 24 hours
Environment of Use	Hospital, extended care facilities, emergency medical services, and patient transport	Hospital, extended care facilities, emergency medical services, and patient transport
Patient Population	Patient population from infant (neonate) to adults	Patient population from neonates to adults
Contraindications	Contraindicated in individuals not requiring elevated end expiratory pressure therapy	Contraindicated in individuals not requiring elevated end expiratory pressure therapy
Features, Specifications, and Performance		
Standard 22 / 30 mm connections	Yes	Yes
Pressure Range (cmH₂O)	Adjustable - 2.5 to 10, 0 to 1, 5 to 20, and 0 to 20	Adjustable - 2.5 to 10, 0 to 1, 5 to 20, and 0 to 20
Principle of Operation	Spring actuated valve	Spring actuated valve
Placement	Placed into a circuit or attached to a manual resuscitator	Placed into a circuit or attached to a manual resuscitator
Leakage	After setting the sample to 5 cm H ₂ O and pressurizing, the pressure drop shall not be in excess of 2 cmH ₂ O within 5 seconds after reaching 5 cmH ₂ O	After setting the sample to 5 cm H ₂ O and pressurizing, the pressure drop shall not be in excess of 2 cmH ₂ O within 5 seconds after reaching 5 cmH ₂ O
Pressure / Accuracy	At flow rates of 2, 3, 5, 10, and 15 lpm the resistance value should when set to 5 cmH ₂ O be 5 +2.5/-2 and when set to 20 cmH ₂ O be 20 +2.5/-2	At flow rates of 2, 3, 5, 10, and 15 lpm the resistance value should when set to 5 cmH ₂ O be 5 +2.5/-2 and when set to 20 cmH ₂ O be 20 +2.5/-2



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WC66-G609
Silver Spring, MD 20993-0002

April 14, 2014

GaleMed Corporation
C/O Mr. Paul Dryden
Amoy Export Processing Zone, 39
Section 3, Haijing East Road
XIAMEN, FUJIAN, CHINA 361026

Re: K133957

Trade/Device Name: Disposable Adjustable PEEP Valve
Regulation Number: 21 CFR 868.5965
Regulation Name: Breathing Attachment Positive End Expiratory Pressure
Regulatory Class: II
Product Code: BYE
Dated: February 12, 2014
Received: February 14, 2014

Dear Mr. Dryden:

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.

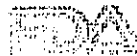
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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,



Digitally signed by Richard
C. Chapman
Date: 2014.04.15 13:17:29
-04'00'

for

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

Enclosure

Indications for Use

510(k) Number (if known)
K133957

Device Name
Disposable Adjustable PEEP Valve

Indications for Use (Describe)

Single patient use adjustable positive end expiratory pressure (PEEP) valves for use in hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.

For use with neonates to adults.

Environment of Use:

Hospital, extended care facilities, emergency medical services, and patient transport

May be used in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



Anya C. Harry -S
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