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Device Classification Name Valve, Non-Rebreathing²²

510(K) Number K152521

Device Name Seal Rite Non-Rebreathing Valve

Applicant The Lifeguard Store, Inc.

2012 W. College Ave.

Normal, IL 61761

Applicant Contact Amy Hilten

Correspondent Quarles & Brady, LLP

33 E Main Street, Suite 900 Madison, WI 53703

|Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵

Correspodent Contact Jennifer J. Hennessy

868.5870²³ **Regulation Number** Classification Product Code CBP²⁴ **Date Received** 09/03/2015 **Decision Date** 06/03/2016

Decision Substantially Equivalent (SESE)

Regulation Medical Specialty Anesthesiology 510k Review Panel Anesthesiology Summary²⁵ **Summary Traditional Type**

Reviewed By Third Party No **Combination Product** No

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- 23. /scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=868.5870
- 24. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=CBP
- 25. http://www.accessdata.fda.gov/cdrh_docs/pdf15/K152521.pdf

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