



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

510(k) Premarket Notification



[510\(k\)|DeNovo](#)⁸ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹|[PMA](#)¹²|[HDE](#)¹³|[Classification](#)¹⁴|[Standards](#)¹⁵
[CFR Title 21](#)¹⁶|[Radiation-Emitting Products](#)¹⁷|[X-Ray Assembler](#)¹⁸|[Medsun Reports](#)¹⁹|[CLIA](#)²⁰|[TPLC](#)²¹

[New Search](#)

[Back To Search Results](#)

Device Classification Name	Valve, Non-Rebreathing ²²
510(K) Number	K142402
Device Name	BigEasy Non-Rebreathing Valve
Applicant	12th Man Technologies, Inc. 7245 Garden Grove Blvd., Suite C Garden Grove, CA 92841
Applicant Contact	Alex Stenzler
Correspondent	12th Man Technologies, Inc. 7245 Garden Grove Blvd., Suite C Garden Grove, CA 92841
Correspondent Contact	Alex Stenzler
Regulation Number	868.5870 ²³
Classification Product Code	CBP ²⁴
Date Received	08/27/2014
Decision Date	03/23/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Anesthesiology
510k Review Panel	Anesthesiology
Summary	Summary ²⁵
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>

EXHIBIT C

15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=CBP
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/pdf14/K142402.pdf

Page Last Updated: 10/10/2016

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#)
[Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#)



U.S. Department of **Health & Human Services**

Links on this page: