

**K163223 ORCA (tm) - Operational Rescue Containment Apparatus**Nov 2, 2017  
351 days to decisionK163223 · Product code: **LGM** · General Hospital  
Source: <https://www.510kdatabase.net/k163223/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Patient Isolation (LGM)
Date received	Nov 16, 2016
Decision date	Nov 2, 2017
Days to decision	351 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Isovac Products, LLC</b>
Location	Bellaire, TX, US
Contact	PETER M. JENKNER
510(k) history	2 submissions · 2 cleared · 2006-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163223/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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