

**K003145 ORIGEN BLADDER HOLDER**Apr 20, 2001  
192 days to decisionK003145 · Product code: **DWC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k003145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Oct 10, 2000
Decision date	Apr 20, 2001
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Origen Biomedical, Inc.</b>
Location	Austin, TX, US
Contact	RICHARD MARTIN
510(k) history	4 submissions · 4 cleared · 2001-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003145/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 14, 2026