

**K011040 CRYOCARE CARDIAC SURGICAL SYSTEM**Jun 15, 2001  
71 days to decisionK011040 · Product code: **OCL** · CardiovascularSource: <https://www.510kdatabase.net/k011040/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Apr 5, 2001
Decision date	Jun 15, 2001
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endocare, Inc.</b>
Location	Irvine, CA, US
Contact	VINCENT CUTARELLI
Website	<a href="http://www.endocare.com/">http://www.endocare.com/</a>
510(k) history	22 submissions · 22 cleared · 1996-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011040/> 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 May 18, 2026