

**K011461 ACCESS CARDIOSYSTEMS MANUAL
DEFIBRILLATOR**May 28, 2002
379 days to decisionK011461 · Product code: **LDD** · Cardiovascular
Source: <https://www.510kdatabase.net/k011461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	May 14, 2001
Decision date	May 28, 2002
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Access Cardiosystems, Inc.
Location	Concord, MA, US
Contact	DAVID BARASH
510(k) history	2 submissions · 1 cleared · 2002-2002

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