

**K010099 ZYNERGY Z3K BALLOON GUIDED PACING AND MONITORING CATHETER**Feb 1, 2001  
21 days to decisionK010099 · Product code: LDF · Cardiovascular  
Source: <https://www.510kdatabase.net/k010099/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Jan 11, 2001
Decision date	Feb 1, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zcv ,Inc.</b>
Location	Edison, NJ, US
Contact	JING ZHANG
510(k) history	6 submissions · 6 cleared · 1999-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010099/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated July 1, 2026