

**K082628 CMR42 CARDIAC MRI IMAGING SYSTEM, 2.1.23**Nov 20, 2008  
72 days to decisionK082628 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k082628/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 9, 2008
Decision date	Nov 20, 2008
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Circle Cardiovascular Imaging, Inc.</b>
Location	Calgary, Alberta, CA
Contact	SHIRANTHA SAMARAPPULI
510(k) history	9 submissions · 9 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082628/> 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 26, 2026