

K072591 CARDIOP-B SYSTEM, VERSION 2.1Oct 10, 2007
26 days to decisionK072591 · Product code: IZI · Radiology
Source: <https://www.510kdatabase.net/k072591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Angiographic (IZI)
Date received	Sep 14, 2007
Decision date	Oct 10, 2007
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paieon, Inc.
Location	New York, NY, US
Contact	RAVIT BARKAMA
510(k) history	8 submissions · 8 cleared · 2004-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072591/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026