FDA 510(k) Premarket Notification

K090493 SIGNAL

CLEARED

Aug 7, 2009
163 days to decision

K090493 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k090493/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Feb 25, 2009
Decision date	Aug 7, 2009
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zargis Medical Corp.**
Location	Princeton, NJ, US
Contact	JOHN KALLASSY
510(k) history	5 submissions · 5 cleared · 2004-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k090493/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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