FDA 510(k) Premarket Notification

K090499 LIFEDOP MODEL, L350R

CLEARED

Mar 31, 2009
34 days to decision

K090499 · Product code: **MAA** · Radiology
Source: https://www.510kdatabase.net/k090499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Fetal Doppler Ultrasound (MAA)
Date received	Feb 25, 2009
Decision date	Mar 31, 2009
Days to decision	34 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Summit Doppler Systems, Inc.**
Location	Arvada, CO, US
Contact	KEN JARRELL
510(k) history	7 submissions · 7 cleared · 2003-2011