

K083382 CHROMA, MODEL: RZ153CAug 13, 2009
272 days to decisionK083382 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k083382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Nov 14, 2008
Decision date	Aug 13, 2009
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scottcare Corporation
Location	Cleveland, OH, US
Contact	TIMOTHY J LEYVA
510(k) history	4 submissions · 4 cleared · 2008-2014

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