

**K212317 Eclipse MINI Model 98900**Nov 7, 2022  
469 days to decisionK212317 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k212317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Jul 26, 2021
Decision date	Nov 7, 2022
Days to decision	469 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spacelabs Healthcare, Ltd.</b>
Location	Nederland, CO, US
Contact	Roger Moldon
510(k) history	9 submissions · 9 cleared · 2011-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Speed TO Market, Inc.</b>
Contact	Thomas Kroenke

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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