FDA 510(k) Premarket Notification

# K211651 Eclipse PRO

**CLEARED**

Nov 22, 2021
178 days to decision

K211651 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k211651/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrocardiograph, Ambulatory (without Analysis) (MWJ) |
| Date received | May 28, 2021 |
| Decision date | Nov 22, 2021 |
| Days to decision | 178 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Speed TO Market, Inc.** |
| Contact | Thomas Kroenke |

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