

**K211709 Biotres**Jan 19, 2022  
230 days to decisionK211709 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k211709/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Jun 3, 2021
Decision date	Jan 19, 2022
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biotricity</b>
Location	Redwood City, CA, US
Contact	Spencer LaDow
510(k) history	3 submissions · 3 cleared · 2020-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211709/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026