

**K193179 EV1000 Clinical Platform**Dec 17, 2019  
29 days to decisionK193179 · Product code: **DXG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193179/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Nov 18, 2019
Decision date	Dec 17, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	Jamie Byun
Website	<a href="https://www.edwards.com">https://www.edwards.com</a>
510(k) history	135 submissions · 129 cleared · 1979-2026

Edwards Lifesciences, LLC is a global structural heart innovation company headquartered in Irvine, California. The company specializes in advanced medical devices for cardiovascular disease management. Edwards Lifesciences has established a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1979. The company's portfolio is dominated by Cardiovascular devices, which represent 88% of all submissions. The latest clearance was received in 2026, demonstrating continued active development and regulatory engagement. Recent clea...

---