

K190078 IntraSightFeb 11, 2019
26 days to decisionK190078 · Product code: **DSA** · Cardiovascular
Source: <https://www.510kdatabase.net/k190078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Jan 16, 2019
Decision date	Feb 11, 2019
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Volcano Corporation
Location	Rancho Cordova,, CA, US
Contact	Kimberly Simon
510(k) history	55 submissions · 55 cleared · 2005-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190078/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026