

K240087 RT Carbon ECG LeadsSep 13, 2024
246 days to decisionK240087 · Product code: **DSA** · Cardiovascular
Source: <https://www.510kdatabase.net/k240087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Jan 11, 2024
Decision date	Sep 13, 2024
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ivy Biomedical Systems, Inc.
Location	Branford, CT, US
Contact	Nathan Middleleer
Website	https://ivybiomedical.com
510(k) history	27 submissions · 27 cleared · 1986-2024

Ivy Biomedical Systems, Inc. is a privately-held medical device company headquartered in Branford, Connecticut. The company is the market leader for precision cardiac gating monitors used for synchronization of radiographic image acquisition across major imaging modalities including nuclear medicine, computed tomography, magnetic resonance, positron emission tomography, and single photon emission computed tomography. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1986. Cardiovascular devices represent the dominant focus,...