

K202138 Cardiac Trigger MonitorMay 14, 2021
287 days to decisionK202138 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k202138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 31, 2020
Decision date	May 14, 2021
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Ivy Biomedical Systems, Inc.
Location	Branford, CT, US
Contact	Alejandra Aceves
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,...