

K880066 MODEL 303D AND 403D ADULT HEART RATE & RESPIRATORMar 22, 1988
71 days to decisionK880066 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k880066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jan 11, 1988
Decision date	Mar 22, 1988
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Ivy Biomedical Systems, Inc.
Location	Branford, CT, US
Contact	BRENDA E LUNDY
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,...

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