

K192852 MRI ECG Patient CableMar 28, 2020
177 days to decisionK192852 · Product code: **LNH** · Cardiovascular
Source: <https://www.510kdatabase.net/k192852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 3, 2019
Decision date	Mar 28, 2020
Days to decision	177 days
Third-party review	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,...

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