

**K912139 MODEL 704**Mar 25, 1992  
316 days to decisionK912139 · Product code: **GWM** · Neurology  
Source: <https://www.510kdatabase.net/k912139/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	May 14, 1991
Decision date	Mar 25, 1992
Days to decision	316 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ivy Biomedical Systems, Inc.</b>
Location	Branford, CT, US
Contact	STEVEN M.SIMON
Website	<a href="https://ivybiomedical.com">https://ivybiomedical.com</a>
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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