

K884662 PATIENT MONITOR MODEL 703Feb 2, 1989
87 days to decisionK884662 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k884662/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrocardiograph (DPS) |
| Date received | Nov 7, 1988 |
| Decision date | Feb 2, 1989 |
| Days to decision | 87 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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Device record: <https://www.510kdatabase.net/k884662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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