

K945099 PARAMETERS MONITORESJul 13, 1995
268 days to decisionK945099 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k945099/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received | Oct 18, 1994 |
| Decision date | Jul 13, 1995 |
| Days to decision | 268 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ivy Biomedical Systems, Inc. |
| Location | Branford, CT, US |
| Contact | DICK LISTRO |
| 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,...
