

K130411 740 SELECTMay 29, 2013
99 days to decisionK130411 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k130411/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Feb 19, 2013 |
| Decision date | May 29, 2013 |
| Days to decision | 99 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Cas Medical Systems, Inc. |
| Location | Branford, CT, US |
| Contact | RON JEFFREY |
| Website | http://www.casmed.com/ |
| 510(k) history | 32 submissions · 32 cleared · 1985-2019 |

Cas Medical Systems, Inc. specialized in cardiovascular devices and critical care monitoring technologies, with a manufacturing facility in Branford, Connecticut. The company developed noninvasive tissue oximetry systems and hemodynamic monitoring solutions for surgical and intensive care settings. The company received FDA 510(k) clearances from total submissions between 1985 and 2019. Its regulatory portfolio focused primarily on tissue oximetry devices for cardiovascular and general surgical applications. The company maintains a strong historical record in critical care...
