

K063087 MODIFICATION TO MODEL 750 SERIES MONITORDec 11, 2006
62 days to decisionK063087 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k063087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Oct 10, 2006
Decision date	Dec 11, 2006
Days to decision	62 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...
