

K091452 FORE-SIGHT, MODEL MC-2000 SERIES (MC 2000, MC2010, MC-2020,MC2030)

Aug 21, 2009
95 days to decision

K091452 · Product code: **MUD** · Cardiovascular
Source: <https://www.510kdatabase.net/k091452/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	May 18, 2009
Decision date	Aug 21, 2009
Days to decision	95 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...