

K180003 FORE-SIGHT ELITE Module Tissue OximeterMay 10, 2018
128 days to decisionK180003 · Product code: **MUD** · Cardiovascular
Source: <https://www.510kdatabase.net/k180003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Jan 2, 2018
Decision date	May 10, 2018
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	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...

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