

K926030 KLEAR-TEMPFeb 24, 1994
450 days to decisionK926030 · Product code: **FMT** · General Hospital
Source: <https://www.510kdatabase.net/k926030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Dec 1, 1992
Decision date	Feb 24, 1994
Days to decision	450 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cas Medical Systems, Inc.
Location	Branford, CT, US
Contact	EDWARD W JACKSON
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...
