

K861364 NEOGUARD ECG ELECTRODESAug 6, 1986
117 days to decisionK861364 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k861364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 11, 1986
Decision date	Aug 6, 1986
Days to decision	117 days
Third-party review	No

APPLICANT

Company	Cas Medical Systems, Inc.
Location	Branford, CT, US
Contact	JOEL N HELFER
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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k861364/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026