FDA 510(k) Premarket Notification

K033283 CENTRA VIEW DEVICE LINK SYSTEM

CLEARED

Oct 27, 2003
13 days to decision

K033283 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k033283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Oct 14, 2003
Decision date	Oct 27, 2003
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Icu Datasystems, Inc.**
Location	Gainesville, FL, US
Contact	SAMUEL W COONS
510(k) history	1 submissions · 1 cleared · 2003-2003