FDA 510(k) Premarket Notification

K831225 GAS-STAT MONITORING SYSTEM

CLEARED

May 27, 1983
42 days to decision

K831225 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k831225/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Apr 15, 1983
Decision date	May 27, 1983
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Cardiovascular Devices, Inc.**
Location	Walker, MI, US
510(k) history	8 submissions · 8 cleared · 1982-1989