FDA 510(k) Premarket Notification

K915265 CDI(TM) H/S CUVETTE, MODIFICATION

CLEARED

Jan 15, 1992
57 days to decision

K915265 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k915265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Nov 19, 1991
Decision date	Jan 15, 1992
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**3M Company**
Location	White City, OR, US
Contact	ANN-MARIE BUTLER
Website	http://www.3m.com/
510(k) history	331 submissions · 322 cleared · 1976-2025