FDA 510(k) Premarket Notification

K910421 SATURATION/HEMATOCRIT MONITOR SYSTEM

CLEARED

Oct 15, 1991
258 days to decision

K910421 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k910421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Jan 30, 1991
Decision date	Oct 15, 1991
Days to decision	258 days
Third-party review	No

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	NORMA LOWE
510(k) history	475 submissions · 453 cleared · 1977-2023