FDA 510(k) Premarket Notification

K900213 PACEMAKER PATIENT ADAPTOR MODULE (PPAM)

CLEARED

Jun 28, 1990
162 days to decision

K900213 · Product code: **DSB** · Cardiovascular
Source: https://www.510kdatabase.net/k900213/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Jan 17, 1990
Decision date	Jun 28, 1990
Days to decision	162 days
Third-party review	No

APPLICANT

Company	**Bomed Medical Mfg., Ltd.**
Location	Irvine, CA, US
Contact	BO SRAMEK
510(k) history	2 submissions · 2 cleared · 1989-1990