FDA 510(k) Premarket Notification

K880498 RM-301 PATIENT MONITOR

CLEARED

May 13, 1988
98 days to decision

K880498 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k880498/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Feb 5, 1988
Decision date	May 13, 1988
Days to decision	98 days
Third-party review	No

APPLICANT

Company	**Ppg Industries, Inc.**
Location	Pleasantville, NY, US
Contact	STEVE BRODY
Website	http://corporate.ppg.com/Home.aspx
510(k) history	20 submissions · 20 cleared · 1987-1992

PPG Industries, Inc. is a global manufacturer of paints, coatings, and specialty products headquartered in Pittsburgh, Pennsylvania, with a manufacturing facility in Pleasantville, US. The company operates in more than 50 countries and reported net sales of $15.9 billion in 2025. PPG Industries received FDA 510(k) clearances from total submissions, with all submissions resulting in clearance. The company's regulatory activity focused on cardiovascular devices, including physiological monitoring systems, recording equipment, and transducer catheters. Clearances span from 1...