FDA 510(k) Premarket Notification

K903917 COMPACT MONITOR SMK 210,211,230,231,240

CLEARED

Jan 18, 1991
147 days to decision

K903917 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k903917/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 24, 1990
Decision date	Jan 18, 1991
Days to decision	147 days
Third-party review	No

APPLICANT

Company	**Ppg Hellige B.V.**
Location	West Germany, DE
Contact	RUDOLF HERZ
510(k) history	3 submissions · 3 cleared · 1991-1993