FDA 510(k) Premarket Notification

K921666 CARDIAC THERAPHY SYSTEM SCP 900

CLEARED

Sep 23, 1993
534 days to decision

K921666 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k921666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Apr 7, 1992
Decision date	Sep 23, 1993
Days to decision	534 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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