FDA 510(k) Premarket Notification

K823828 THERACARD 400

CLEARED

Mar 17, 1983
87 days to decision

K823828 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k823828/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Dec 20, 1982
Decision date	Mar 17, 1983
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
510(k) history	778 submissions · 778 cleared · 1980-2026