FDA 510(k) Premarket Notification

K840258 TEC-3500 DEFIBRILLATOR

CLEARED

May 23, 1984
121 days to decision

K840258 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k840258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Jan 23, 1984
Decision date	May 23, 1984
Days to decision	121 days
Third-party review	No

APPLICANT

Company	**Nihon Kohden America, Inc.**
Location	Foothill Ranch, CA, US
510(k) history	166 submissions · 163 cleared · 1979-2012