

K840258 TEC-3500 DEFIBRILLATORMay 23, 1984
121 days to decisionK840258 · Product code: **LDD** · CardiovascularSource: <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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k840258/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026