FDA 510(k) Premarket Notification

K971355 NIHON KOHDEN TEC-7531 CARDIOLIFE PORTABLE DEFIBRILLATOR AND ACCESSORIES

CLEARED

Jul 15, 1997
95 days to decision

K971355 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k971355/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Apr 11, 1997
Decision date	Jul 15, 1997
Days to decision	95 days
Third-party review	No

APPLICANT

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