

**K971194 NIHON KOHDEN TEC-6100A CARDIOLIFE MINI
DEFIBRILLATOR & ACCESSORIES**

Jul 9, 1997
99 days to decision

K971194 · Product code: **LDD** · Cardiovascular
Source: <https://www.510kdatabase.net/k971194/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Apr 1, 1997
Decision date	Jul 9, 1997
Days to decision	99 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k971194/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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