FDA 510(k) Premarket Notification

K970787 ALEXANDER MFG. RECHARGEABLE BATTERY (MODEL M3)

CLEARED

May 14, 1997
71 days to decision

K970787 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k970787/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 4, 1997
Decision date	May 14, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Alexander Mfg. Co.**
Location	Mason City, IA, US
Contact	STACEY HIPPEN
510(k) history	39 submissions · 37 cleared · 1997-1998