

K942629 NCE REPLACEMENT BATTERIESAug 18, 1994
76 days to decisionK942629 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k942629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jun 3, 1994
Decision date	Aug 18, 1994
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	National Custom Ent., Inc.
Location	Burnsville, MN, US
Contact	MICHAEL A BENYO
510(k) history	12 submissions · 11 cleared · 1993-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942629/> 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 July 1, 2026