

K922064 MODEL #510 STEALTH-PLATE DISPERSIVE ELECTRODEDec 1, 1992
211 days to decisionK922064 · Product code: **GXD** · Neurology
Source: <https://www.510kdatabase.net/k922064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Lesion, Radiofrequency (GXD)
Date received	May 4, 1992
Decision date	Dec 1, 1992
Days to decision	211 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cardiotronics, Inc.
Location	West Carlsbad, CA, US
Contact	TIM J WAY
510(k) history	27 submissions · 27 cleared · 1988-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922064/> 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