FDA 510(k) Premarket Notification

K922064 MODEL #510 STEALTH-PLATE DISPERSIVE ELECTRODE

CLEARED

Dec 1, 1992
211 days to decision

K922064 · 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