FDA 510(k) Premarket Notification

K060661 MACTRODE 3

CLEARED

Apr 7, 2006
25 days to decision

K060661 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k060661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Mar 13, 2006
Decision date	Apr 7, 2006
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
Contact	KAREN RUSSELL
510(k) history	136 submissions · 132 cleared · 1978-2012