FDA 510(k) Premarket Notification

K100315 12 LEAD GLOVE

CLEARED

Apr 23, 2010
78 days to decision

K100315 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k100315/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 4, 2010
Decision date	Apr 23, 2010
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**I Needmd, Inc.**
Location	New York, NY, US
Contact	IRVING L WIESEN, ESQ
510(k) history	1 submissions · 1 cleared · 2010-2010