FDA 510(k) Premarket Notification

K961013 DISPOSABLE NEEDLE ELECTRODE

CLEARED

Dec 20, 1996
282 days to decision

K961013 · Product code: **IKT** · Neurology
Source: https://www.510kdatabase.net/k961013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Mar 13, 1996
Decision date	Dec 20, 1996
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medelec Intl. Corp.**
Location	Miami Beach, FL, US
Contact	JEFF HALL
510(k) history	15 submissions · 15 cleared · 1985-1996