

K961013 DISPOSABLE NEEDLE ELECTRODEDec 20, 1996
282 days to decisionK961013 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961013/> 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 June 30, 2026