

K080914 ULTRASHARP CONCENTRIC NEEDLESJul 15, 2008
105 days to decisionK080914 · Product code: **IKT** · Neurology
Source: <https://www.510kdatabase.net/k080914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Apr 1, 2008
Decision date	Jul 15, 2008
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rochester Electro Medical, Inc.
Location	Lutz, FL, US
Contact	CHARLES C BERKINS
510(k) history	2 submissions · 2 cleared · 2008-2015

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