

**K002992 DISPOSABLE HYPODERMIC NEEDLE ELECTRODE,  
 MODEL 9013S0421,9013S0431,9013S0441,9013S0451,9013S046  
 1,1013S0421,103S0431**

Aug 15, 2001  
 324 days to decision

K002992 · Product code: **IKT** · Neurology  
 Source: <https://www.510kdatabase.net/k002992/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Sep 25, 2000
Decision date	Aug 15, 2001
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Functional Diagnostics A/S</b>
Location	Skovlunde, DK
Contact	TOVE KJAER
510(k) history	11 submissions · 11 cleared · 1999-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k002992/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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