CLEARED

K002992 DISPOSABLE HYPODERMIC NEEDLE ELECTRODE, MODEL 9013S0421,9013S0431,9013S0441,9013S0451,9013S0461,1013S0421,103S0431

Aug 15, 2001
324 days to decision

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

SUBMISSION DETAILS

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

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