

**K253581 Disposable Concentric Needle Electrode 0.30x25mm
Red (TE/B50700-001)**Mar 15, 2026
118 days to decisionK253581 · Product code: **IKT** · Neurology
Source: <https://www.510kdatabase.net/k253581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Nov 17, 2025
Decision date	Mar 15, 2026
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Disposable Concentric Needle Electrode 0.40x25mm Yellow (TE/B50700-002); Disposable Concentric Needle Electrode 0.30x30mm Pink (TE/B50700-006); Disposable Concentric Needle Electrode 0.45x37mm Green (TE/B50700-003); Disposable Concentric Needle Electrode 0.45x50mm Blue (TE/B50700-004); Disposable Concentric Needle Electrode 0.60x75mm Violet (TE/B50700-005)

APPLICANT

Company	Technomed Europe
Location	Kerkrade, NL
Contact	Alan Yik
510(k) history	12 submissions · 12 cleared · 1999-2026

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