

**K861861 515A NEO-TRAK NEONATAL MONITOR**Jul 10, 1986  
57 days to decisionK861861 · Product code: **KLK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k861861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	May 14, 1986
Decision date	Jul 10, 1986
Days to decision	57 days
Third-party review	No

**APPLICANT**

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Company	<b>Ge Medical Systems Information Technologies</b>
Location	Mchenry, IL, US
Contact	JOSEPH P LENZEN
510(k) history	136 submissions · 132 cleared · 1978-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861861/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026