

**K800164 413A NEONATAL MONITOR**Apr 10, 1980  
76 days to decisionK800164 · Product code: **FLS** · AnesthesiologySource: <https://www.510kdatabase.net/k800164/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Apnea, Facility Use (FLS)
Date received	Jan 25, 1980
Decision date	Apr 10, 1980
Days to decision	76 days
Third-party review	No

**APPLICANT**

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Company	<b>Xerox Corp.</b>
Location	Walker, MI, US
Website	<a href="http://www.xerox.com">http://www.xerox.com</a>
510(k) history	2 submissions · 2 cleared · 1980-1983

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k800164/>; 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 21, 2026