

**K800631 OXYMETER**Apr 2, 1980  
13 days to decisionK800631 · Product code: **KLK** · AnesthesiologySource: <https://www.510kdatabase.net/k800631/>**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	Mar 20, 1980
Decision date	Apr 2, 1980
Days to decision	13 days
Third-party review	No

**APPLICANT**

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Company	<b>Dragerwerk AG</b>
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1980-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k800631/> 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 28, 2026