

**K800988 NOVAMETRIX TCOMETTE #809 TRANS. MONITOR**May 28, 1980  
34 days to decisionK800988 · Product code: **KLK** · AnesthesiologySource: <https://www.510kdatabase.net/k800988/>**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         | Apr 24, 1980  |
| Decision date         | May 28, 1980  |
| Days to decision      | 34 days   |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Novamatrix Medical Systems, Inc.</b> |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 45 submissions · 45 cleared · 1978-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k800988/> 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 25, 2026