

**K980384 TRIP TONOMETRY CATHETER, 18F**May 1, 1998  
88 days to decisionK980384 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k980384/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK) |
| Date received         | Feb 2, 1998  |
| Decision date         | May 1, 1998  |
| Days to decision      | 88 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Datex-Engstrom, Inc.</b>           |
| Location       | Tewksbury, MA, US                     |
| Contact        | JOEL C KENT                           |
| 510(k) history | 9 submissions · 9 cleared · 1998-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980384/> 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