

**K810682 PENTAX COLONOSCOPE MODEL FC-34LA**Apr 3, 1981  
21 days to decisionK810682 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k810682/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Colonoscope And Accessories, Flexible/rigid (FDF) |
| Date received         | Mar 13, 1981                                      |
| Decision date         | Apr 3, 1981                                       |
| Days to decision      | 21 days   |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Pentax Precision Instrument Corp.</b> |
| Location       | Mchenry, IL, US                          |
| 510(k) history | 67 submissions · 67 cleared · 1979-2004  |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k810682/> 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 18, 2026