

**K953286 FCP-9P, FIBER CHOLEDOCHOSCOPE**Nov 3, 1995  
113 days to decisionK953286 · Product code: **FBN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k953286/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Traditional   |
| Device classification | Choledochoscope And Accessories, Flexible/rigid (FBN) |
| Date received         | Jul 13, 1995  |
| Decision date         | Nov 3, 1995   |
| Days to decision      | 113 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Pentax Precision Instrument Corp.</b> |
| Location       | Mchenry, IL, US                          |
| Contact        | PAUL SILVA                               |
| 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/k953286/> 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