

**K822765 SIGMOIDOSCOPE, FLEXIBLE**Nov 17, 1982  
64 days to decisionK822765 · Product code: **FAM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k822765/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Sigmoidoscope And Accessories, Flexible/rigid (FAM) |
| Date received         | Sep 14, 1982  |
| Decision date         | Nov 17, 1982  |
| Days to decision      | 64 days   |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Harvard Laboratories</b>           |
| Location       | Mchenry, IL, US                       |
| 510(k) history | 8 submissions · 8 cleared · 1980-1982 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k822765/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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