

**K952414 PREFILLED SYRINGE FOR INFLATION OF FOLEY CATHETER**Jun 23, 1995  
31 days to decisionK952414 · Product code: **KNY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k952414/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Accessories, Catheter, G-u (KNY)   |
| Date received         | May 23, 1995                       |
| Decision date         | Jun 23, 1995                       |
| Days to decision      | 31 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Acacia Laboratories, Inc.</b>        |
| Location       | Santa Ana, CA, US                       |
| Contact        | BEN WALTHALL                            |
| 510(k) history | 12 submissions · 10 cleared · 1988-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952414/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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