

**K072594 GYRUS ACMI IPN-2505, INVISIO SMITH  
PERCUTANEOUS NEPHROSCOPE SYSTEM**Dec 13, 2007  
90 days to decisionK072594 · Product code: **FGA** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k072594/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Kit, Nephroscope (FGA)             |
| Date received         | Sep 14, 2007                       |
| Decision date         | Dec 13, 2007                       |
| Days to decision      | 90 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Gyrus Acmi, Inc.</b>   |
| Location       | Westborough, MA, US   |
| Contact        | GRAHAM A BAILLIE  |
| Website        | <a href="https://www.olympusmedical.com">https://www.olympusmedical.com</a> |
| 510(k) history | 42 submissions · 42 cleared · 2007-2026                                     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072594/> 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 June 26, 2026