

**K090601 FSC 2**May 11, 2009  
67 days to decisionK090601 · Product code: **NTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k090601/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Led Light Source (NTN)             |
| Date received         | Mar 5, 2009                        |
| Decision date         | May 11, 2009                       |
| Days to decision      | 67 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Schoelly Imaging, Inc.</b>         |
| Location       | Ayer, MA, US                          |
| Contact        | F. DAVID ROTHKOPF                     |
| 510(k) history | 5 submissions · 5 cleared · 2006-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090601/> 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 23, 2026