

**K082805 PAGUAMEDICINA STRUCTURAL HYDROGEL  
PEDIATRIC URETERAL STENT, MODEL NP330-XXX**Jan 20, 2010  
483 days to decisionK082805 · Product code: **FAD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k082805/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Stent, Ureteral (FAD)              |
| Date received         | Sep 24, 2008                       |
| Decision date         | Jan 20, 2010                       |
| Days to decision      | 483 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Q Urological Corporation</b>       |
| Location       | Natick, MA, US                        |
| Contact        | SCOTT M EPSTEIN                       |
| 510(k) history | 3 submissions · 3 cleared · 2010-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082805/> Data sourced from FDA 510(k) public records (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 31, 2026