

K933268 CANDELA GUIDEWIREFeb 10, 1994
219 days to decisionK933268 · Product code: **NWU** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k933268/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscope Introducer Kit (NWU) |
| Date received | Jul 6, 1993 |
| Decision date | Feb 10, 1994 |
| Days to decision | 219 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Candela Laser Corp. |
| Location | Wayland, MA, US |
| Contact | THOMAS R VARRICCHIONE |
| 510(k) history | 43 submissions · 43 cleared · 1988-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k933268/> 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. - Generated June 29, 2026