

K910732 CANDELA MINI-UB ENDOSCOPEApr 12, 1991
50 days to decisionK910732 · Product code: **ODF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k910732/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mini Endoscope, Gastroenterology-urology (ODF) |
| Date received | Feb 21, 1991 |
| Decision date | Apr 12, 1991 |
| Days to decision | 50 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910732/>; 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