

**K950633 CANDELA URETHRAL/BLADDER SOUND**Mar 6, 1995  
21 days to decisionK950633 · Product code: **FBX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k950633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sound, Urethral, Metal Or Plastic (FBX)
Date received	Feb 13, 1995
Decision date	Mar 6, 1995
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950633/> 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 30, 2026