

**K950634 CANDELA SHEATH SETS**Mar 1, 1995  
16 days to decisionK950634 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k950634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 13, 1995
Decision date	Mar 1, 1995
Days to decision	16 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/k950634/> 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 29, 2026