

**K950635 CANDEKA DUKATIR SETS**Mar 1, 1995  
16 days to decisionK950635 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k950635/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| 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**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950635/> 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