FDA 510(k) Premarket Notification

# K013284 LUMEND FRONTRUNNER CTO CORONARY CATHETER

**CLEARED**

Feb 11, 2002
132 days to decision

K013284 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k013284/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Oct 2, 2001 |
| Decision date | Feb 11, 2002 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Lumend, Inc.** |
| Location | Redwood City, CA, US |
| Contact | MICHAEL A DANIEL |
| 510(k) history | 11 submissions · 11 cleared · 2001-2005 |