

K142199 Ascendra Balloon Aortic Valvuloplasty CatheterOct 29, 2014
79 days to decisionK142199 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k142199/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Balloon Aortic Valvuloplasty (OZT) |
| Date received | Aug 11, 2014 |
| Decision date | Oct 29, 2014 |
| Days to decision | 79 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------------|
| Company | Edwards Lifesciences |
| Location | Irvine, CA, US |
| Contact | Susan Reynolds |
| Website | http://www.edwards.com |
| 510(k) history | 20 submissions · 19 cleared · 2011-2026 |

Edwards Lifesciences is the leading global structural heart innovation company dedicated to improving patient lives through breakthrough cardiovascular technologies. The company partners with physicians to develop products for patients fighting heart disease, with a manufacturing facility in Irvine, US. Edwards Lifesciences has received FDA 510(k) clearances from total submissions since 2011. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance in 2025 reflects continued innovation and acti...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142199/> 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 May 25, 2026