

K993248 AMPLATZER SIZING BALLOONJul 12, 2000
288 days to decisionK993248 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k993248/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular Occluding, Temporary (MJN) |
| Date received | Sep 28, 1999 |
| Decision date | Jul 12, 2000 |
| Days to decision | 288 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Aga Medical Corp. |
| Location | Plymouth, MN, US |
| Contact | JODI L LOCHER |
| 510(k) history | 14 submissions · 14 cleared · 2000-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993248/> 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 June 14, 2026