

**K112587 ADVANCED PERFUSION SYSTEM 1 (APS1) TUBE
CLAMP ASSEMBLY, ROLLER PUMP 6 INCH CLASSIC COLOR,**Dec 19, 2011
104 days to decisionK112587 · Product code: **DWB** · Cardiovascular
Source: <https://www.510kdatabase.net/k112587/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Blood, Cardiopulmonary Bypass, Roller Type (DWB) |
| Date received | Sep 6, 2011 |
| Decision date | Dec 19, 2011 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Terumo Cardiovascular Systems Corp. |
| Location | Elkton, MD, US |
| Contact | REBECCA ANDERSEN |
| 510(k) history | 43 submissions · 43 cleared · 2000-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112587/> 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