

**K101186 AFFINITY VARD SUB-ASSEMBLY FOR CPS
(CARMEDA COATED), PURGELINE (UNCOATED), HOLDING
BAG**Sep 3, 2010
128 days to decisionK101186 · Product code: **DTP** · Cardiovascular
Source: <https://www.510kdatabase.net/k101186/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Defoamer, Cardiopulmonary Bypass (DTP) |
| Date received | Apr 28, 2010 |
| Decision date | Sep 3, 2010 |
| Days to decision | 128 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Perfusion Systems |
| Location | Minneapolis, MN, US |
| Contact | CARALEE WALTON |
| 510(k) history | 29 submissions · 29 cleared · 2000-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101186/>; 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 14, 2026