

**K915547 SARNs 8000 DELPHIN II CENTRI PUMP MOD  
W/INTEGR BAT**Sep 9, 1993  
638 days to decisionK915547 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k915547/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Dec 11, 1991
Decision date	Sep 9, 1993
Days to decision	638 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>3M Health Care, Sarns</b>
Location	Mchenry, IL, US
Contact	JAMES BALUN
510(k) history	76 submissions · 76 cleared · 1976-1996

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915547/>. 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 29, 2026