

**K811004 MANIFOLD**May 8, 1981  
25 days to decisionK811004 · Product code: **DTZ** · CardiovascularSource: <https://www.510kdatabase.net/k811004/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 13, 1981
Decision date	May 8, 1981
Days to decision	25 days
Third-party review	No

**APPLICANT**

---

Company	<b>American Pharmaseal Div. Ahsc</b>
Location	Mchenry, IL, US
510(k) history	64 submissions · 61 cleared · 1980-1987

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k811004/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 22, 2026