

**K833918 INFUSION PORT BALLOON THERMODILUTION**Jan 30, 1984  
77 days to decisionK833918 · Product code: **DYG** · CardiovascularSource: <https://www.510kdatabase.net/k833918/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Nov 14, 1983
Decision date	Jan 30, 1984
Days to decision	77 days
Third-party review	No

**APPLICANT**

---

Company	<b>Critikon Company, LLC</b>
Location	Mchenry, IL, US
510(k) history	51 submissions · 51 cleared · 1979-2000

---

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

Device record: <https://www.510kdatabase.net/k833918/> 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 26, 2026