

**K863730 MYOLEX**Oct 15, 1986  
22 days to decisionK863730 · Product code: **DDR** · Immunology  
Source: <https://www.510kdatabase.net/k863730/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Sep 23, 1986
Decision date	Oct 15, 1986
Days to decision	22 days
Third-party review	No

**APPLICANT**

---

Company	<b>Orion Corp.</b>
Location	20101 Turku, FL
Contact	TIMO RAINES
510(k) history	21 submissions · 20 cleared · 1985-1992

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863730/>, 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 21, 2026