

**K022176 ORION DIAGNOSTICA ULTRASENSITIVE CRP KIT,  
MODEL 68025, & ORION DIAGNOSTICA ULTRASENSITIVE CRP  
CONTROL, MODEL 68257**Dec 3, 2002  
153 days to decisionK022176 · Product code: **DCK** · Immunology  
Source: <https://www.510kdatabase.net/k022176/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jul 3, 2002
Decision date	Dec 3, 2002
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Orion Diagnostica, Div. Orion Corp.</b>
Location	02101 Espoo, FI
Contact	ANNIKKA RANTAMA
510(k) history	4 submissions · 4 cleared · 1995-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k022176/> 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 June 29, 2026