CLEARED

K022176 ORION DIAGNOSTICA ULTRASENSITIVE CRP KIT, MODEL 68025, & ORION DIAGNOSTICA ULTRASENSITIVE CRP CONTROL, MODEL 68257

Dec 3, 2002
153 days to decision

K022176 · 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	**Orion Diagnostica, Div. Orion Corp.**
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Contact	ANNIKKA RANTAMA
510(k) history	4 submissions · 4 cleared · 1995-2003