

**K970695 ACS:180 BR (AUTOMATED CHEMILUMINESCENCE SYSTEM FOR THE QUANTITATION OF CANCER ANTIGEN 27.29)**Aug 8, 1997  
164 days to decisionK970695 · Product code: **MOI** · Immunology  
Source: <https://www.510kdatabase.net/k970695/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Feb 25, 1997
Decision date	Aug 8, 1997
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chiron Diagnostics Corp.</b>
Location	Medfield, MA, US
Contact	DIANE C OATES
510(k) history	20 submissions · 20 cleared · 1997-1999

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