

K981839 ACS:CENTAUR PSA2 IMMUNOASSAYAug 12, 1998
78 days to decisionK981839 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k981839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	May 26, 1998
Decision date	Aug 12, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chiron Diagnostics Corp.
Location	Medfield, MA, US
Contact	William J Pignato
510(k) history	20 submissions · 20 cleared · 1997-1999

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