FDA 510(k) Premarket Notification

K982680 CHIRON DIAGNOSTICS CORPORATION ACS: CENTAUR BR IMMUNOASSAY

CLEARED

Oct 15, 1998
76 days to decision

K982680 · Product code: **MOI** · Immunology
Source: https://www.510kdatabase.net/k982680/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Jul 31, 1998
Decision date	Oct 15, 1998
Days to decision	76 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k982680/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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