

K970386 ACS ESTADIOL-6 IIJun 4, 1997
121 days to decisionK970386 · Product code: **CHP** · Chemistry
Source: <https://www.510kdatabase.net/k970386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Feb 3, 1997
Decision date	Jun 4, 1997
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Chiron Diagnostics Corp.
Location	Medfield, MA, US
Contact	THOMAS F FLYNN
510(k) history	20 submissions · 20 cleared · 1997-1999

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