

K850712 EMIT QST PHENYTOIN ASSAY -MONOCLONAL ANTIBODYMar 20, 1985
26 days to decisionK850712 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k850712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Feb 22, 1985
Decision date	Mar 20, 1985
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	JOAN KURJIAN
510(k) history	448 submissions · 447 cleared · 1976-2001

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