

K913562 QMS - DIGOXINAug 30, 1991
21 days to decisionK913562 · Product code: **LCS** · Chemistry
Source: <https://www.510kdatabase.net/k913562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (125-i) (LCS)
Date received	Aug 9, 1991
Decision date	Aug 30, 1991
Days to decision	21 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Seradyn, Inc.
Location	Indianapolis, IN, US
Contact	MICHAEL SULLIVAN
510(k) history	28 submissions · 28 cleared · 1988-2007

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