

K011972 DIRECT BILIRUBIN REAGENTAug 27, 2001
63 days to decisionK011972 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k011972/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 25, 2001
Decision date	Aug 27, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Intersect Systems, Inc.
Location	Mchenry, IL, US
Contact	MARK E LEGAZ
510(k) history	21 submissions · 21 cleared · 1983-2002

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