

K972382 UB ANALYZER UA-2, REAGENT KIT AND BILIRUBIN CONTROL

Sep 14, 1998
445 days to decision

K972382 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k972382/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 26, 1997
Decision date	Sep 14, 1998
Days to decision	445 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arrows Co., Ltd.
Location	Osaka, JP
Contact	YOSHIMASA OGOSHI
510(k) history	1 submissions · 1 cleared · 1998-1998

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Device record: <https://www.510kdatabase.net/k972382/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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