

K884224 TOTAL BILIRUBIN REAGENT KIT FOR ASTRA SYSTEMSDec 15, 1988
70 days to decisionK884224 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k884224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Oct 6, 1988
Decision date	Dec 15, 1988
Days to decision	70 days
Third-party review	No

APPLICANT

Company	A-Kem, Inc.
Location	Clifton, NJ, US
Contact	STEVEN LEE
510(k) history	13 submissions · 13 cleared · 1987-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884224/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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