

K922770 UNISTAT BILIRUBINOMETER MODELS 10310 AND 10311Aug 18, 1992
70 days to decisionK922770 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k922770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Jun 9, 1992
Decision date	Aug 18, 1992
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Leica, Inc.
Location	Buffalo, NY, US
Contact	JOHN CROCKER
510(k) history	3 submissions · 3 cleared · 1992-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922770/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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