

**K830977 HELENA BIOSTRIP P**Apr 28, 1983  
30 days to decisionK830977 · Product code: **JIR** · Chemistry  
Source: <https://www.510kdatabase.net/k830977/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator Method, Protein Or Albumin (urinary, Non-quant.) (JIR)
Date received	Mar 29, 1983
Decision date	Apr 28, 1983
Days to decision	30 days
Third-party review	No

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k830977/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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