

K926222 OWREN'S VERONAL BUFFER #5375 & FIBRINOGEN KIT#5376Feb 12, 1993
64 days to decisionK926222 · Product code: JPA · Hematology
Source: <https://www.510kdatabase.net/k926222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Dec 10, 1992
Decision date	Feb 12, 1993
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k926222/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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