

**K021162 AMAX DENSITY COAGULATION ANALYZER, AMAX
DENSTINY COAGULATION ANALYZER-EU, AMAX DESTINY
COAGULATION ANALYZER-REFURBISHED**Aug 30, 2002
141 days to decisionK021162 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k021162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Apr 11, 2002
Decision date	Aug 30, 2002
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT II
510(k) history	164 submissions · 164 cleared · 1984-2002

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