

K911434 THROMBONOSTIKA F1.2Oct 31, 1991
212 days to decisionK911434 · Product code: **MIF** · Hematology
Source: <https://www.510kdatabase.net/k911434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prothrombin Fragment 1.2 (MIF)
Date received	Apr 2, 1991
Decision date	Oct 31, 1991
Days to decision	212 days
Third-party review	No

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	THOMAS S CLEMENT
510(k) history	130 submissions · 129 cleared · 1980-2000

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