

K072288 PATHFAST D-DIMERMay 6, 2009
629 days to decisionK072288 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k072288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Aug 16, 2007
Decision date	May 6, 2009
Days to decision	629 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mitsubishi Kagaku Iatron
Location	Seattle, WA, US
Contact	HELEN LANDICHO
510(k) history	4 submissions · 4 cleared · 2008-2009

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