

K853388 MONOSTICON UNI-DOTAug 22, 1985
9 days to decisionK853388 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k853388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Aug 13, 1985
Decision date	Aug 22, 1985
Days to decision	9 days
Third-party review	No

APPLICANT

Company	Organon, Inc.
Location	Mchenry, IL, US
Contact	PATRICK J OSINSKI
510(k) history	41 submissions · 41 cleared · 1977-1995

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