

K072901 AMDL-ELISA DR-70 (FDP) IMMUNOASSAY, MODEL DR2101Jul 1, 2008
264 days to decisionK072901 · Product code: **NTY** · Immunology
Source: <https://www.510kdatabase.net/k072901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Fibrin/fibrinogen Degradation Products For Monitoring Of Colorectal Cancer (NTY)
Date received	Oct 11, 2007
Decision date	Jul 1, 2008
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amdl, Inc.
Location	Tustin, CA, US
Contact	GARY DREHER
510(k) history	2 submissions · 2 cleared · 1998-2008

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