

K012163 POLYTITER SYSTEMAug 20, 2001
40 days to decisionK012163 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k012163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Jul 11, 2001
Decision date	Aug 20, 2001
Days to decision	40 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Polymedco, Inc.
Location	Cortlandt Manor, NY, US
Contact	HELLEN LANDICHO
510(k) history	19 submissions · 19 cleared · 1992-2011

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