

K926114 HEP-2 ANTINUCLEAR ANTIBODY TEST SYSTEMMay 20, 1993
168 days to decisionK926114 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k926114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Dec 3, 1992
Decision date	May 20, 1993
Days to decision	168 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tissue Culture Biotec, Inc.
Location	Bozeman, MT, US
Contact	PETER NAPHTHINE
510(k) history	1 submissions · 1 cleared · 1993-1993

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