

K070763 EUROIMMUN ANA IFA: HEP-20-10May 22, 2007
63 days to decisionK070763 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k070763/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Mar 20, 2007
Decision date	May 22, 2007
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Euroimmun Us, LLC
Location	Boonton Twp, NJ, US
Contact	KATHRYN KOHL
510(k) history	6 submissions · 6 cleared · 2006-2007

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