

K160265 Image Navigator by Immuno ConceptsJun 17, 2016
136 days to decisionK160265 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k160265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Feb 2, 2016
Decision date	Jun 17, 2016
Days to decision	136 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immuno Concepts, N.A. , Ltd.
Location	Dallas, TX, US
Contact	Eric S. Hoy
510(k) history	4 submissions · 4 cleared · 2003-2023

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