

K203599 Image Navigator by Immuno Concepts, Immuno Concepts IgG Anti-nDNA Fluorescent Test SystemMay 26, 2023
898 days to decisionK203599 · Product code: KTL · Immunology
Source: <https://www.510kdatabase.net/k203599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Indirect Immunofluorescent Solid Phase (KTL)
Date received	Dec 9, 2020
Decision date	May 26, 2023
Days to decision	898 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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