

**K873708 FIAX TEST KIT FOR ENA (RNP/SM) ANTIBODIES**Nov 25, 1987  
71 days to decisionK873708 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k873708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Sep 15, 1987
Decision date	Nov 25, 1987
Days to decision	71 days
Third-party review	No

**APPLICANT**

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Company	<b>Whittaker Bioproducts, Inc.</b>
Location	Walkersville, MD, US
Contact	LOUISE M HARRIS
510(k) history	30 submissions · 30 cleared · 1984-1992

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