

K971458 ENZIP IMMUNOTURBIDIMETRIC MICROALBUMIN ASSAY KIT

Sep 2, 1997
133 days to decision

K971458 · Product code: **JIQ** · Chemistry
Source: <https://www.510kdatabase.net/k971458/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Turbidimetric Method, Protein Or Albumin (urinary, Non-quant.) (JIQ)
Date received	Apr 22, 1997
Decision date	Sep 2, 1997
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Specialties
Location	Mchenry, IL, US
Contact	RINALDO PAGNUCCO
510(k) history	8 submissions · 8 cleared · 1981-1997

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Device record: <https://www.510kdatabase.net/k971458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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