

K840758 IMPULSE THEOPHYLLINE ASSAY REAGENTSApr 4, 1984
41 days to decisionK840758 · Product code: **LER** · Toxicology
Source: <https://www.510kdatabase.net/k840758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Theophylline (LER)
Date received	Feb 23, 1984
Decision date	Apr 4, 1984
Days to decision	41 days
Third-party review	No

APPLICANT

Company	Paragon Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1984-1984

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Device record: <https://www.510kdatabase.net/k840758/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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