

**K864835 TAKANE AUTO ENEMATOR MODELS
1200R/G1300TR/G1300SR***

Feb 11, 1987
64 days to decision

K864835 · Product code: **FCD** · Radiology
Source: <https://www.510kdatabase.net/k864835/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barium Enema Kit (FCD)
Date received	Dec 9, 1986
Decision date	Feb 11, 1987
Days to decision	64 days
Third-party review	No

APPLICANT

Company	Eisai U.S.A., Inc.
Location	Torrance, CA, US
Contact	MINORU ABE
510(k) history	1 submissions · 1 cleared · 1987-1987

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Device record: <https://www.510kdatabase.net/k864835/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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