

K834059 FUKUDA DENSHI EH-11Jun 21, 1985
574 days to decisionK834059 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k834059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Nov 25, 1983
Decision date	Jun 21, 1985
Days to decision	574 days
Third-party review	No

APPLICANT

Company	Fukuda Denshi USA, Inc.
Location	Mchenry, IL, US
510(k) history	68 submissions · 68 cleared · 1984-2018

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Device record: <https://www.510kdatabase.net/k834059/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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