

K812021 VOLUMETRIC INFUSION PUMPJul 31, 1981
11 days to decisionK812021 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k812021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jul 20, 1981
Decision date	Jul 31, 1981
Days to decision	11 days
Third-party review	No

APPLICANT

Company	American Edwards Laboratories
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987

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Device record: <https://www.510kdatabase.net/k812021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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