

**K972135 MAERSK MEDICAL PURELINE COMFORT
SUBCUTANEOUS INFUSION SET**

Aug 26, 1997
81 days to decision

K972135 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k972135/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jun 6, 1997
Decision date	Aug 26, 1997
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	P/L Biomedical
Location	Fort Myers, FL, US
510(k) history	3 submissions · 3 cleared · 1997-2012

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Device record: <https://www.510kdatabase.net/k972135/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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