

**K941684 IVEX-2 EXTENSION SET WITH Y-INJECTION SITE**Aug 3, 1994  
121 days to decisionK941684 · Product code: **FPB** · General Hospital  
Source: <https://www.510kdatabase.net/k941684/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Infusion Line (FPB)
Date received	Apr 4, 1994
Decision date	Aug 3, 1994
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	FREDERICK A GUSTAFSON
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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