

K003827 PUNCTUR-GUARD WINGED SET FOR BLOOD COLLECTIONJan 8, 2001
28 days to decisionK003827 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k003827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 11, 2000
Decision date	Jan 8, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Plexus, Inc.
Location	Tolland, CT, US
Contact	PAUL A TENTHOREY
510(k) history	6 submissions · 6 cleared · 1990-2001

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