

K011580 SIMPLICITY SOFT QD SILVER INFUSION SETJun 5, 2001
14 days to decisionK011580 · Product code: **FPA** · General Hospital
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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 22, 2001
Decision date	Jun 5, 2001
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterling Medivations, Inc.
Location	Wayzata, MN, US
Contact	JOEL S DOUGLAS
510(k) history	27 submissions · 27 cleared · 2000-2002

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