

K180843 HigH-Flo Super26 Subcutaneous Needle SetsApr 4, 2019
367 days to decisionK180843 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k180843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 2, 2018
Decision date	Apr 4, 2019
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Repro-Med Systems, Inc. DbA Rms Medical Products
Location	New York, NY, US
Contact	Cynthia Lacatena
510(k) history	3 submissions · 3 cleared · 2013-2019

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