

K180720 Medifine Pen Needle 3 BevelJun 27, 2018
100 days to decisionK180720 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k180720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 19, 2018
Decision date	Jun 27, 2018
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary
Other names	Medifine Pen Needle Quinta 5 Bevel

APPLICANT

Company	Medibio USA, LLC
Location	Cooper City, FL, US
Contact	Jatin Rajani
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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