

K190996 Bonus Therapeutics Mixing and Delivery SystemJul 28, 2019
103 days to decisionK190996 · Product code: **FMF** · Orthopedic
Source: <https://www.510kdatabase.net/k190996/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 16, 2019
Decision date	Jul 28, 2019
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bonus Therapeutics , Ltd.
Location	Haifa, IL
Contact	Nir Shtayer
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190996/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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