

K201900 3D GraftRasp SystemSep 3, 2020
57 days to decisionK201900 · Product code: **FMF** · Orthopedic
Source: <https://www.510kdatabase.net/k201900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 8, 2020
Decision date	Sep 3, 2020
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Surgentec
Location	Boca Raton, FL, US
Contact	Andrew Shoup
510(k) history	3 submissions · 3 cleared · 2020-2023

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