FDA 510(k) Premarket Notification

CLEARED

K243580 GraftGun Universal Graft Delivery System (GDS)

Feb 5, 2025
78 days to decision

K243580 · Product code: **FMF** · Orthopedic
Source: https://www.510kdatabase.net/k243580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 19, 2024
Decision date	Feb 5, 2025
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**SurGenTec, LLC**
Location	Boca Raton, FL, US
Contact	Jason Hershman
Website	https://www.surgentec.com
510(k) history	23 submissions · 23 cleared · 2017-2026

SurGenTec, LLC is a medical device manufacturer specializing in orthopedic surgical solutions. The company operates with a manufacturing facility in Boca Raton, US. SurGenTec has received FDA 510(k) clearances from total submissions since its first clearance in 2017. Orthopedic devices represent 78% of the company's regulatory portfolio. The company remains actively engaged in FDA 510(k) submissions, with its most recent clearance in 2026. SurGenTec's product portfolio includes fusion systems, graft delivery instruments, bone void fillers, and specialized surgical navigat...