FDA 510(k) Premarket Notification

CLEARED

K170675 Graftgun Universal Graft Delivery System

Jul 19, 2017
135 days to decision

K170675 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k170675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 6, 2017
Decision date	Jul 19, 2017
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**SurGenTec, LLC**
Location	Boca Raton, FL, US
Contact	Travis Greenhalgh
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...