FDA 510(k) Premarket Notification

CLEARED

K200064 OsteoFlo NanoPutty-Quadphasic Synthetic Bone Graft

Aug 14, 2020
214 days to decision

K200064 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k200064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jan 13, 2020
Decision date	Aug 14, 2020
Days to decision	214 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...