FDA 510(k) Premarket Notification

CLEARED

K243835 TiLink-P SI Joint Fusion System

Dec 27, 2024
14 days to decision

K243835 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k243835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 13, 2024
Decision date	Dec 27, 2024
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**SurGenTec, LLC**
Location	Boca Raton, FL, US
Contact	Berny Villejeune
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...