FDA 510(k) Premarket Notification

K190163 ALARA Neuro Access Kit

CLEARED

Jul 16, 2019
166 days to decision

K190163 · Product code: **PDQ** · Neurology
Source: https://www.510kdatabase.net/k190163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Jan 31, 2019
Decision date	Jul 16, 2019
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**SurGenTec, LLC**
Location	Boca Raton, FL, US
Contact	Travis Greenhalgh
Website	https://www.surgentec.com
510(k) history	24 submissions · 24 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...

REGULATORY CONSULTANT

Consulting firm	**Quality Solutions and Support, LLC**
Contact	Stephen Inglese

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov