FDA 510(k) Premarket Notification

CLEARED

K192979 KLS Martin Individual Patient Solutions (IPS) Planning System

Mar 11, 2020
139 days to decision

K192979 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k192979/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Oct 24, 2019
Decision date	Mar 11, 2020
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**KLS-Martin L.P.**
Location	Jacksonville, FL, US
Contact	Jennifer Damato
Website	https://www.klsmartin.com
510(k) history	78 submissions · 78 cleared · 1994-2026

KLS-Martin L.P. is a surgical device manufacturer based in Jacksonville, US. The company specializes in surgical innovation across orthopedic, dental, and neurology device categories. KLS-Martin has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company maintains active regulatory status, with its latest FDA 510(k) clearance in 2026. Core product areas include orthopedic implants and fixation systems, dental implants and surgical instruments, and neurosurgical devices including cranial implants and expansion systems. Notable r...