

K230211 CranioXpandNov 21, 2023
299 days to decisionK230211 · Product code: **PBJ** · Neurology
Source: <https://www.510kdatabase.net/k230211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Distraction System (PBJ)
Date received	Jan 26, 2023
Decision date	Nov 21, 2023
Days to decision	299 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	KLS-Martin L.P.
Location	Jacksonville, FL, US
Contact	Melissa Bachorski
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...