

K221938 KLS Martin Pure Pectus SystemMar 28, 2023
270 days to decisionK221938 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k221938/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 1, 2022
Decision date	Mar 28, 2023
Days to decision	270 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...

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Device record: <https://www.510kdatabase.net/k221938/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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