

K210228 KLS Martin IPS PreprostheticJul 8, 2022
526 days to decisionK210228 · Product code: **ELE** · Dental
Source: <https://www.510kdatabase.net/k210228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Subperiosteal (ELE)
Date received	Jan 28, 2021
Decision date	Jul 8, 2022
Days to decision	526 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	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...

REGULATORY CONSULTANT

Consulting firm	KLS Martin L.P.
Contact	Susan Leander

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

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Device record: <https://www.510kdatabase.net/k210228/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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