

K252573 KLS Martin Cranial Implants - MR ConditionalNov 10, 2025
88 days to decisionK252573 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k252573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Aug 14, 2025
Decision date	Nov 10, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	K944565: KLS-Martin Micro Osteosynthesis System (1.5MM); K971297: KLS Martin Centre-Drive Drill-Free Screw; K060177: KLS Martin Rigid Fixation - Sterile; K062570: Individual Patient Solutions - Ti (IPS-Ti); K072707: Individual Patient Solutions - PEEK (IPS-PEEK) ; K151382: Individual Patient Solutions - (IPS-PEEK) - STERILE

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...