FDA 510(k) Premarket Notification

CLEARED

K151382 Patient Contoured Implant-PEEK (PCI-PEEK)

Nov 9, 2015
171 days to decision

K151382 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k151382/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	May 22, 2015
Decision date	Nov 9, 2015
Days to decision	171 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...