

K251959 TnR Cranial Implant

Jul 30, 2026
399 days to decision

K251959 · Product code: **GXP** · Neurology
Source: <https://www.510kdatabase.net/k251959/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Jun 26, 2025
Decision date	Jul 30, 2026
Days to decision	399 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	T&R BIOFAB CO., Ltd.
Location	Siheung-Si, KR
Contact	Chaewon Park
510(k) history	2 submissions · 2 cleared · 2023-2026