FDA 510(k) Premarket Notification

K240567 CustomizedBone Service

CLEARED

Mar 28, 2024
28 days to decision

K240567 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k240567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Feb 29, 2024
Decision date	Mar 28, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fin-Ceramica Faenza S.P.A.**
Location	Faenza, IT
Contact	Marina Monticelli
510(k) history	5 submissions · 5 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	**Fortrea**
Contact	Stephanie Perryman

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