

K212058 Longeviti ClearFit™ OTS Cranial ImplantsSep 8, 2021
69 days to decisionK212058 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k212058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jul 1, 2021
Decision date	Sep 8, 2021
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Longeviti Neuro Solutions, LLC
Location	Hunt Valley, MD, US
Contact	Heather Hourihan
510(k) history	8 submissions · 8 cleared · 2018-2023

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