

**K170410 Longeviti PMMA Static Cranial Implant**Mar 23, 2018  
406 days to decisionK170410 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k170410/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Feb 10, 2017
Decision date	Mar 23, 2018
Days to decision	406 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Longeviti Neuro Solutions, LLC</b>
Location	Hunt Valley, MD, US
Contact	Kevin Lee
510(k) history	8 submissions · 8 cleared · 2018-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170410/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026