

**K250420 Helios Dura Regeneration Matrix**May 14, 2025  
90 days to decisionK250420 · Product code: **GXQ** · Neurology  
Source: <https://www.510kdatabase.net/k250420/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Feb 13, 2025
Decision date	May 14, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Helios Biomedical, Inc.</b>
Location	Weston, MA, US
Contact	Yiannis Monovoukas
510(k) history	2 submissions · 2 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>QUARAS, LLC</b>
Contact	Roshana Ahmed

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

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