FDA 510(k) Premarket Notification

K250420 Helios Dura Regeneration Matrix

CLEARED

May 14, 2025
90 days to decision

K250420 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k250420/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**QUARAS, LLC**
Contact	Roshana Ahmed

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