FDA 510(k) Premarket Notification

K250397 Helios Dermal Scaffold

CLEARED

Aug 15, 2025
184 days to decision

K250397 · Product code: **KGN** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250397/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Feb 12, 2025
Decision date	Aug 15, 2025
Days to decision	184 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