

K251844 Kerecis SurgiBind (50241)Jul 15, 2025
29 days to decisionK251844 · Product code: **OXH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Collagen, Plastic And Reconstructive Surgery (OXH)
Date received	Jun 16, 2025
Decision date	Jul 15, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kerecis Limited
Location	Isafjordur, IS
Contact	Skuli Magnusson
510(k) history	10 submissions · 10 cleared · 2013-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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