

K202430 Kerecis ReconstructMay 2, 2021
250 days to decisionK202430 · Product code: **OXH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202430/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Plastic And Reconstructive Surgery (OXH)
Date received	Aug 25, 2020
Decision date	May 2, 2021
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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