

K153364 Kerecis SecureMeshAug 19, 2016
273 days to decisionK153364 · Product code: **OXE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Staple Line Reinforcement (OXE)
Date received	Nov 20, 2015
Decision date	Aug 19, 2016
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153364/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026