FDA 510(k) Premarket Notification

K153364 Kerecis SecureMesh

CLEARED

Aug 19, 2016
273 days to decision

K153364 · Product code: **OXE** · General & Plastic Surgery
Source: 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