

K213904 Kerecis OralSep 30, 2022
290 days to decisionK213904 · Product code: **NPL** · DentalSource: <https://www.510kdatabase.net/k213904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Dec 14, 2021
Decision date	Sep 30, 2022
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kerecis
Location	Isafjordur, IS
Contact	Gudmundur Fertram Sigurjonsson
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213904/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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