

K211554 InnoGenic Non-resorbable MembraneFeb 24, 2023
646 days to decisionK211554 · Product code: **NPK** · Dental
Source: <https://www.510kdatabase.net/k211554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	May 19, 2021
Decision date	Feb 24, 2023
Days to decision	646 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cowellmedi Co., Ltd.
Location	Newington, NH, US
Contact	Minjin Park
510(k) history	14 submissions · 14 cleared · 2004-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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