

K221808 InterOss CollagenMar 18, 2023
269 days to decisionK221808 · Product code: **NPM** · Dental
Source: <https://www.510kdatabase.net/k221808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Animal Source (NPM)
Date received	Jun 22, 2022
Decision date	Mar 18, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sigmagraft, Inc.
Location	Brea, CA, US
Contact	Elcin Chang
510(k) history	3 submissions · 3 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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

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