

K202675 InRoad® Dental Synthetic Bone GraftMar 4, 2022
535 days to decisionK202675 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k202675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Sep 15, 2020
Decision date	Mar 4, 2022
Days to decision	535 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osteogene Tech Corp
Location	Norwood, NJ, US
Contact	Daniel S. Oh
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Jmc Medical, LLC
Contact	James L. O' Connor

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

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