

K192941 HySil Super Fast Impression MaterialsJan 30, 2020
104 days to decisionK192941 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k192941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Oct 18, 2019
Decision date	Jan 30, 2020
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Co., Ltd.
Location	Busan, KR
Contact	Jungmin Yoo
Website	https://www.osstem.com
510(k) history	68 submissions · 68 cleared · 2006-2026

REGULATORY CONSULTANT

Consulting firm	Hiossen, Inc.
Contact	Peter Lee

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

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