

K160097 Image Fast Set, Image Regular SetAug 5, 2016
199 days to decisionK160097 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k160097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jan 19, 2016
Decision date	Aug 5, 2016
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sybron Dental Specialties
Location	Newport Beach, CA, US
Contact	Gerardo Lara
510(k) history	15 submissions · 15 cleared · 2006-2018

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