

K183542 Signature Orthodontic SystemJan 2, 2019
13 days to decisionK183542 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k183542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Dec 20, 2018
Decision date	Jan 2, 2019
Days to decision	13 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Signature Orthodontics
Location	Boston, MA, US
Contact	Alfred Charles Griffin
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Mark Job

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

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