

K181271 Signature Orthodontic SystemJun 13, 2018
30 days to decisionK181271 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k181271/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bracket, Ceramic, Orthodontic (NJM) |
| Date received | May 14, 2018 |
| Decision date | Jun 13, 2018 |
| Days to decision | 30 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

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|-----------------|--|
| 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181271/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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