

K190394 SunClear Aligner systemDec 16, 2019
300 days to decisionK190394 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k190394/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Aligner, Sequential (NXC) |
| Date received | Feb 19, 2019 |
| Decision date | Dec 16, 2019 |
| Days to decision | 300 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sun Dental Laboratories, LLC |
| Location | St. Petersburg, FL, US |
| Contact | Derek Diasti |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Sun Dental Laboratories, LLC / Promedic, LLC |
| Contact | Paul Dryden |

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/k190394/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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