

K192029 Straumann PUREloc abutmentsOct 28, 2019
90 days to decisionK192029 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k192029/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Jul 30, 2019 |
| Decision date | Oct 28, 2019 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Institut Straumann AG |
| Location | Basel, CH |
| Contact | Giulia Oran |
| Website | https://www.straumann.com |
| 510(k) history | 90 submissions · 90 cleared · 1990-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------------|
| Consulting firm | Straumann USA, LLC |
| Contact | Jennifer M Jackson |

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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