

K250771 Primescan 2Aug 29, 2025
169 days to decisionK250771 · Product code: **NTK** · Dental
Source: <https://www.510kdatabase.net/k250771/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Caries Detector, Laser Light, Transmission (NTK) |
| Date received | Mar 13, 2025 |
| Decision date | Aug 29, 2025 |
| Days to decision | 169 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dentsply Sirona, Inc. |
| Location | York, PA, US |
| Contact | Diane Rutherford |
| Website | http://www.dentsply.com |
| 510(k) history | 21 submissions · 21 cleared · 2019-2026 |

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