

**K171634 Ortho System**Jan 17, 2018  
229 days to decisionK171634 · Product code: **PNN** · Dental  
Source: <https://www.510kdatabase.net/k171634/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Orthodontic Software (PNN)         |
| Date received         | Jun 2, 2017                        |
| Decision date         | Jan 17, 2018                       |
| Days to decision      | 229 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>3Shape A/S</b>                     |
| Location       | Copenhagen, DK                        |
| Contact        | Antje Marquardsen                     |
| 510(k) history | 8 submissions · 8 cleared · 2016-2020 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026