

**K051464 PLANMECA PROMAX WITH DEC (DYNAMIC EXPOSURE CONTROL)**Jun 24, 2005  
21 days to decisionK051464 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k051464/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Unit, X-ray, Extraoral With Timer (EHD) |
| Date received         | Jun 3, 2005                             |
| Decision date         | Jun 24, 2005                            |
| Days to decision      | 21 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Planmeca Oy</b>                      |
| Location       | Helsinki, FI                            |
| Contact        | BOB PIENKOWSKI                          |
| 510(k) history | 28 submissions · 28 cleared · 1993-2023 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051464/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026