

**K091628 OPTIMAX, COMPACT 2, OPTIMAX 2010, ECOMAX**Aug 21, 2009  
78 days to decisionK091628 · Product code: **IXW** · Radiology  
Source: <https://www.510kdatabase.net/k091628/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Processor, Radiographic-film, Automatic (IXW) |
| Date received         | Jun 4, 2009                                   |
| Decision date         | Aug 21, 2009                                  |
| Days to decision      | 78 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Protec GmbH &amp; Co. KG</b>       |
| Location       | Oberstenfeld, DE                      |
| Contact        | JOCHEN KRUPP                          |
| 510(k) history | 2 submissions · 2 cleared · 1999-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091628/> 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 17, 2026