

**K000454 DIMEX 2**Mar 31, 2000  
49 days to decisionK000454 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k000454/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Feb 11, 2000
Decision date	Mar 31, 2000
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000454/> 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 19, 2026