

**K261540 Cube 4D Navigation System, VirtuEye Pro**Jun 2, 2026  
25 days to decisionK261540 · Product code: **PGW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k261540/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	May 8, 2026
Decision date	Jun 2, 2026
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fiagon GmbH</b>
Location	Hennigsdorf, DE
Contact	Magdalena Giba
510(k) history	16 submissions · 16 cleared · 2014-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261540/> 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 June 28, 2026