

**K161491 Scopis Hybrid Navigation System EM**Feb 9, 2017  
253 days to decisionK161491 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k161491/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jun 1, 2016
Decision date	Feb 9, 2017
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scopis GmbH</b>
Location	Berlin, DE
Contact	Christopher Ozbek
510(k) history	2 submissions · 2 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161491/> 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 31, 2026