

**K141456 THE FIAGON NAVIGATION - EXTENDED INSTRUMENT  
SET ENT, REGISTRATION POINTER, VENTERA POINTER,  
GUIDEWIRE, POINTERSHELL**Oct 8, 2014  
128 days to decisionK141456 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k141456/>**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 2, 2014
Decision date	Oct 8, 2014
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fiagon GmbH</b>
Location	Hennigsdorf, DE
Contact	DIRK MUCHA
510(k) history	15 submissions · 15 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141456/>; 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 26, 2026