

**K163416 Fiagon Navigation – PointerTube Straight and PointerTube Keat**Feb 16, 2017  
73 days to decisionK163416 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k163416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Dec 5, 2016
Decision date	Feb 16, 2017
Days to decision	73 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/k163416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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