

K161940 Guidewire 0.6 Single UseSep 18, 2016
66 days to decisionK161940 · Product code: **PGW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k161940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jul 14, 2016
Decision date	Sep 18, 2016
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fiagon GmbH
Location	Hennigsdorf, DE
Contact	Dirk Mucha
510(k) history	15 submissions · 15 cleared · 2014-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161940/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026