

K160479 PointerShell Universal, PointerShell LSMar 23, 2016
30 days to decisionK160479 · Product code: **PGW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k160479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Feb 22, 2016
Decision date	Mar 23, 2016
Days to decision	30 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

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