

K200041 FlexPointer 1.5 Single Use, FlexTube 3 Single UseMar 10, 2020
62 days to decisionK200041 · Product code: **PGW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k200041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jan 8, 2020
Decision date	Mar 10, 2020
Days to decision	62 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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