

K193118 TGS Guidewire and updated Scopis SoftwareFeb 21, 2020
101 days to decisionK193118 · Product code: **PGW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k193118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Nov 12, 2019
Decision date	Feb 21, 2020
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Ent
Location	Plymouth, MN, US
Contact	Bruce Backlund
510(k) history	3 submissions · 3 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193118/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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