

**K221098 Scopis ENT Software, Scopis ENT Software with TGS,
Scopis Planning Software, Electromagnetic Navigation Unit**Jul 12, 2022
89 days to decisionK221098 · Product code: **PGW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k221098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Apr 14, 2022
Decision date	Jul 12, 2022
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	Maya Schiel
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...