

**K170018 StealthStation™ S8 ENT Software**May 19, 2017  
136 days to decisionK170018 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k170018/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jan 3, 2017
Decision date	May 19, 2017
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Navigation, Inc.</b>
Location	Lafayette, CO, US
Contact	K. Elizabeth Waite
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
510(k) history	35 submissions · 35 cleared · 2005-2026

Medtronic Navigation, Inc. is based in Lafayette, US. The company specializes in surgical navigation and imaging systems for minimally invasive procedures. The company has received FDA 510(k) clearances from total submissions since 2005. Neurology devices represent a dominant category, including cranial and laser ablation systems. The latest clearance in 2026 reflects continued regulatory activity and product innovation. Recent cleared devices span multiple surgical specialties. StealthStation and Stealth AXiS™ platforms serve neurology, orthopedic, and ear, nose, and thr...

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