

**K192397 TruDi Navigation System**Jan 30, 2020  
149 days to decisionK192397 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k192397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Sep 3, 2019
Decision date	Jan 30, 2020
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosense Webster</b>
Location	Diamond Bar, CA, US
Contact	David Locke
510(k) history	3 submissions · 3 cleared · 2014-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Acclarent, Inc.</b>
Contact	David Locke

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192397/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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