

K161701 CARTO ENT SystemOct 24, 2016
126 days to decisionK161701 · Product code: **PGW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k161701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jun 20, 2016
Decision date	Oct 24, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosense Webster
Location	Diamond Bar, CA, US
Contact	MELISSA C. SCHULTZ
510(k) history	3 submissions · 3 cleared · 2014-2020

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