

**K172492 Optical Topography System ETG-4100**Aug 17, 2018  
365 days to decisionK172492 · Product code: **DQA** · Neurology  
Source: <https://www.510kdatabase.net/k172492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 17, 2017
Decision date	Aug 17, 2018
Days to decision	365 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi Healthcare Americas</b>
Location	Twinsburg, OH, US
Contact	Doug Thistlethwaite
510(k) history	12 submissions · 12 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172492/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026