

**K162595 Trex\_HD**Nov 4, 2016  
50 days to decisionK162595 · Product code: **GWQ** · Neurology  
Source: <https://www.510kdatabase.net/k162595/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Sep 15, 2016
Decision date	Nov 4, 2016
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Natus Medical Incorporated Db a Excel-Tech Ltd. (Xitek)</b>
Location	Oakville, CA
Contact	Sanjay Mehta
510(k) history	13 submissions · 13 cleared · 2016-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162595/> 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 25, 2026