

**K163652 ePlex Instrument**Jun 9, 2017  
168 days to decisionK163652 · Product code: **NSU** · Microbiology  
Source: <https://www.510kdatabase.net/k163652/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation For Clinical Multiplex Test Systems (NSU)
Date received	Dec 23, 2016
Decision date	Jun 9, 2017
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Genmark Diagnostics, Incorporated</b>
Location	Carlsbad, CA, US
Contact	Alan Maderazo
510(k) history	7 submissions · 7 cleared · 2016-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163652/> 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 27, 2026