

**K171313 EM-4000 Specular Microscope**Jan 19, 2018  
260 days to decisionK171313 · Product code: **NQE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k171313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microscope, Specular (NQE)
Date received	May 4, 2017
Decision date	Jan 19, 2018
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tomey Corporation</b>
Location	Tokyo, JP
Contact	Tomoko Watanabe
510(k) history	5 submissions · 5 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171313/> 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