

**K162636 Marco Ultra M3, Marco Ultra M4**Apr 14, 2017  
205 days to decisionK162636 · Product code: **HJO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k162636/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biomicroscope, Slit-lamp, Ac-powered (HJO)
Date received	Sep 21, 2016
Decision date	Apr 14, 2017
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Takagi Seiko Co., Ltd.</b>
Location	Adelaide, South Australia, AU
Contact	HAGIWARA TORU
510(k) history	5 submissions · 5 cleared · 2007-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162636/> 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 June 28, 2026