

**K133797 QMASTER-H/REVO**Sep 4, 2014  
265 days to decisionK133797 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k133797/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 13, 2013
Decision date	Sep 4, 2014
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Telesystems Co., Ltd.</b>
Location	Ormond Beach, FL, US
Contact	Claude Berthoin
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133797/> 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 16, 2026