

K151612 NewTom VGi evoMar 31, 2016
290 days to decisionK151612 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k151612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jun 15, 2015
Decision date	Mar 31, 2016
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qr S.R.L.
Location	Verona, IT
Contact	LORENZO BORTOLOTTI
510(k) history	4 submissions · 4 cleared · 2011-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151612/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026