

**K093105 VISTEO**Oct 18, 2010  
382 days to decisionK093105 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k093105/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Oct 1, 2009
Decision date	Oct 18, 2010
Days to decision	382 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Owandy</b>
Location	Ormond Beach, FL, US
Contact	JAY MANSOUR
510(k) history	6 submissions · 6 cleared · 2006-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093105/> 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