

**K150823 EDLENi Intra-Oral Sensor**Aug 26, 2015  
152 days to decisionK150823 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k150823/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Mar 27, 2015
Decision date	Aug 26, 2015
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edlen Imaging, LLC</b>
Location	Phoenix, AZ, US
Contact	Nick Radachi
510(k) history	3 submissions · 3 cleared · 2011-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150823/> 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