

**K103181 ZENIS, PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM**Aug 26, 2011  
302 days to decisionK103181 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k103181/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 28, 2010
Decision date	Aug 26, 2011
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Genoray Co., Ltd.</b>
Location	Flintville, TN, US
Contact	JAE KIM
510(k) history	24 submissions · 24 cleared · 2007-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103181/> 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 17, 2026