

**K162268 Senographe Pristina**Nov 3, 2016  
83 days to decisionK162268 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k162268/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Aug 12, 2016
Decision date	Nov 3, 2016
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ge Healthcare</b>
Location	Waukesha, WI, US
Contact	Gregory Pessato
Website	<a href="http://www3.gehealthcare.com/en">http://www3.gehealthcare.com/en</a>
510(k) history	168 submissions · 168 cleared · 2004-2026

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...

---