

**K183013 Vitrea Software Package, VSTP-001A**Nov 26, 2018  
26 days to decisionK183013 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k183013/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 31, 2018
Decision date	Nov 26, 2018
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Canon Medical Systems Corporation</b>
Location	Otawara-Shi, JP
Contact	Paul Biggins
Website	<a href="https://global.medical.canon">https://global.medical.canon</a>
510(k) history	96 submissions · 96 cleared · 2018-2026

Canon Medical Systems Corporation is a Japanese medical equipment manufacturer based in Ōtawara, Tochigi. Now part of Canon Inc. following its 2016 acquisition, the company continues to operate as a leading provider of diagnostic imaging systems. Canon Medical Systems has received FDA 510(k) clearances from total submissions since 2018. The company specializes exclusively in Radiology devices, with its latest clearance in 2026, demonstrating continued regulatory activity and product innovation. The company's product portfolio centers on advanced imaging technologies incl...

---