FDA 510(k) Premarket Notification

K203312 Vitrea Software Package, VSTP-001A

CLEARED

Feb 16, 2021
98 days to decision

K203312 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k203312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 10, 2020
Decision date	Feb 16, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

Canon Medical Systems Corporation is a Japanese medical equipment manufacturer based in ÅŒtawara, 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...

REGULATORY CONSULTANT

Consulting firm	**Canon Medical Systems USA, Inc.**
Contact	Orlando Tadeo, Jr.

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov