FDA 510(k) Premarket Notification

CLEARED

K232835 Aquilion ONE (TSX-308A/3) V1.4 with PIQE Reconstruction System

Apr 2, 2024
201 days to decision

K232835 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k232835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 14, 2023
Decision date	Apr 2, 2024
Days to decision	201 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**
Contact	Orlando Tadeo Jr

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