FDA 510(k) Premarket Notification

K203743 EXA

CLEARED

Dec 10, 2021
353 days to decision

K203743 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k203743/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 22, 2020
Decision date	Dec 10, 2021
Days to decision	353 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Konica Minolta Healthcare Americas, Inc.**
Location	Garner, NC, US
Contact	Carolyn Russell
510(k) history	5 submissions · 5 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**MEDIcept, Inc.**
Contact	Scott Blood

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