

**K203743 EXA**Dec 10, 2021  
353 days to decisionK203743 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k203743/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>MEDIcept, Inc.</b>
Contact	Scott Blood

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

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